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(71) Applicant (for all designated States except US): TRIAGE MEDICAL, INC. [US/US]; 13700 Alton Parkway, Ste. 160, Irvine, California 92618 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): MIRKOVIC, Srdjan [US/US]; 575 Oaktree Lane, Northfield, Illinois 60093 (US). CULBERT, Brad, S. [CA/US]; 18 Ballantree, Rancho Santa Margarita, California 92688 (US). WARREN, Christopher, R. [US/US]; 18 Openview, Aliso Viejo, California 92656 (US).

(74) Agent: DELANEY, Karoline, A.; KNOBBE, MARTENS, OLSON &amp; BEAR, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614 (US).

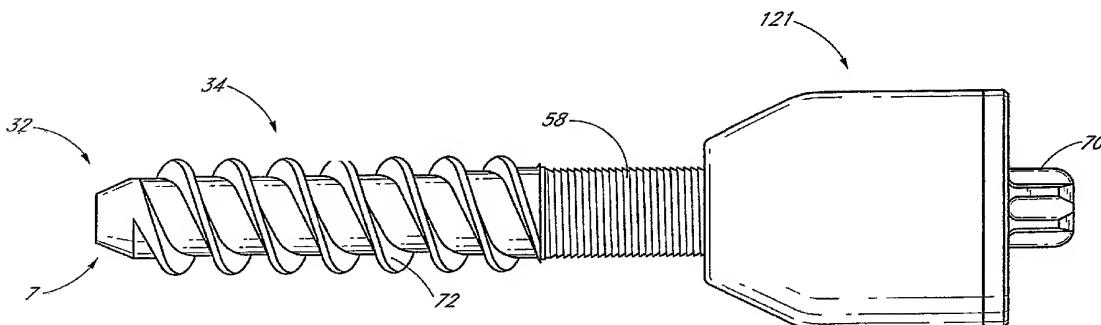
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(54) Title: METHOD AND APPARATUS FOR SPINAL STABILIZATION



(57) Abstract: A method and apparatus of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient includes advancing a distal end of a stabilization device into a pedicle of the inferior vertebrae. A proximal portion of the stabilization device is positioned such that the proximal portion limits at least one degree of movement between a superior vertebrae by contacting a surface of the superior vertebrae.

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## METHOD AND APPARATUS FOR SPINAL STABILIZATION

### PRIORITY INFORMATION

**[0001]** This application is a continuation-in-part of U.S. Patent Application No. 11/185,442, filed July 20, 2005, which is a continuation-in-part of U.S. Patent Application No. 11/059,991, filed February 11, 2005, which claims the priority benefit under 35 U.S.C. § 119(e) of Provisional Application 60/634,203 filed December 8, 2004, the contents of these applications are hereby incorporated by reference herein.

#### Background of the Invention

#### Field of the Invention

**[0002]** The present invention relates to medical devices and, more particularly, to methods and apparatuses for spinal stabilization.

#### Description of the Related Art

**[0003]** The human spine is a flexible weight bearing column formed from a plurality of bones called vertebrae. There are thirty three vertebrae, which can be grouped into one of five regions (cervical, thoracic, lumbar, sacral, and coccygeal). Moving down the spine, there are generally seven cervical vertebra, twelve thoracic vertebra, five lumbar vertebra, five sacral vertebra, and four coccygeal vertebra. The vertebra of the cervical, thoracic, and lumbar regions of the spine are typically separate throughout the life of an individual. In contrast, the vertebra of the sacral and coccygeal regions in an adult are fused to form two bones, the five sacral vertebra which form the sacrum and the four coccygeal vertebra which form the coccyx.

**[0004]** In general, each vertebra contains an anterior, solid segment or body and a posterior segment or arch. The arch is generally formed of two pedicles and two laminae, supporting seven processes--four articular, two transverse, and one spinous. There are exceptions to these general characteristics of a vertebra. For example, the first cervical vertebra (atlas vertebra) has neither a body nor spinous process. In addition, the second cervical vertebra (axis vertebra) has an odontoid process, which is a strong, prominent process, shaped like a tooth, rising perpendicularly from the upper surface of the body of the axis vertebra. Further details regarding the construction of the spine may be found in such common references as Gray's Anatomy, Crown Publishers, Inc., 1977, pp. 33-54, which is herein incorporated by reference.

**[0005]** The human vertebrae and associated connective elements are subjected to a variety of diseases and conditions which cause pain and disability. Among these diseases and conditions are spondylosis, spondylolisthesis, vertebral instability, spinal stenosis and degenerated, herniated, or degenerated and herniated intervertebral discs. Additionally, the vertebrae and associated connective elements are subject to injuries, including fractures and torn ligaments and surgical manipulations, including laminectomies.

**[0006]** The pain and disability related to the diseases and conditions often result from the displacement of all or part of a vertebra from the remainder of the vertebral column. Over the past two decades, a variety of methods have been developed to restore the displaced vertebra to their normal position and to fix them within the vertebral column. Spinal fusion is one such method. In spinal fusion, one or more of the vertebra of the spine are united together ("fused") so that motion no longer occurs between them. The vertebra may be united with various types of fixation systems. These fixation systems may include a variety of longitudinal elements such as rods or plates that span two or more vertebrae and are affixed to the vertebrae by various fixation elements such as wires, staples, and screws (often inserted through the pedicles of the vertebrae). These systems may be affixed to either the posterior or the anterior side of the spine. In other applications, one or more bone screws may be inserted through adjacent vertebrae to provide stabilization.

**[0007]** Although spinal fusion is a highly documented and proven form of treatment in many patients, there is currently a great interest in surgical techniques that provide stabilization of the spine while allowing for some degree of movement. In this manner, the natural motion of the spine can be preserved, especially for those patients with mild or moderate disc conditions. In certain types of these techniques, flexible materials are used as fixation rods to stabilize the spine while permitting a limited degree of movement.

**[0008]** Notwithstanding the variety of efforts in the prior art described above, these techniques are associated with a variety of disadvantages. In particular, these techniques typically involve an open surgical procedure, which results higher cost, lengthy in-patient hospital stays and the pain associated with open procedures.

[0009] Therefore, there remains a need for improved techniques and systems for stabilization the spine. Preferably, the devices are implantable through a minimally invasive procedure.

Summary of the Invention

[0010] Accordingly, one embodiment of the present invention comprises a method of limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient. A distal end of a stabilization device is advanced into a pedicle of the inferior vertebral body. A proximal portion of the stabilization device is positioned such that the proximal portion limits at least one degree of movement between a superior vertebral body and an inferior vertebral body by contacting a surface of the superior vertebral body.

[0011] Another embodiment of the present invention also comprises a method of limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient. A distal end of a first stabilization device is advanced into a pedicle of the inferior vertebral body. A proximal portion of the first stabilization device is positioned such that the proximal portion abuts against a surface of an inferior articular process of the superior adjacent vertebral body to limit at least one degree of movement between a superior vertebral body and an inferior vertebral body. A distal end of a second stabilization device is advanced into a pedicle of the inferior vertebral body such that it is positioned with bilateral symmetry with respect to the first stabilization device. A proximal portion of the second stabilization device is positioned such that the proximal portion abuts, with bilateral symmetry with respect to the first stabilization device, against a surface of a second inferior articular process of the superior adjacent vertebral body to limit at least one degree of movement between the superior vertebral body and the inferior vertebral body.

[0012] Another embodiment of the present invention comprises a spinal stabilization device that includes an elongate body, having a proximal end and a distal end. A distal anchor is on the distal end of the elongate body. A retention structure is on the body, proximal to the distal anchor. A proximal anchor is moveably carried by the body. The proximal anchor has an outer surface with at least a portion of the outer surface being elastic. At least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the

proximal anchor but resisting distal movement of the body with respect the proximal anchor.

**[0013]** Another embodiment of the present invention comprises a spinal stabilization device for limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient. The device includes an elongate body that has a proximal end and a distal end. A distal anchor is positioned on the distal end of the elongate body. A retention structure is on the body, proximal to the distal anchor. A proximal anchor is moveably carried by the body. The proximal anchor includes at least one flat surface configured to abut against a surface of the inferior articular process of the superior adjacent vertebral body when the stabilization device is inserted into the inferior adjacent vertebral body. At least one complementary retention structure is on the proximal anchor and is configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

**[0014]** Yet another embodiment of the present invention comprises a spinal stabilization device for limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient. The device comprises an elongate body, having a proximal end and a distal end. A distal anchor is on the distal end of the elongate body. A retention structure is positioned on the body, proximal to the distal anchor. A proximal anchor is moveably carried by the body. The proximal anchor includes at least one saddle-shaped surface configured to abut against an inferior articular process of the superior adjacent vertebral body when the stabilization device is inserted into the inferior adjacent vertebral body. At least one complementary retention structure is on the proximal anchor and is configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

**[0015]** Another one embodiment of the present invention comprises a method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient. In the embodiment, a distal end of a stabilization device is advanced into a pedicle of the inferior vertebra. A proximal portion of the stabilization device is positioned such that the proximal portion limits at least one degree of movement between the superior vertebrae and the inferior vertebrae by contacting a surface of the superior vertebrae. A portion of the superior vertebrae or the inferior vertebrae is

removed to disperse forces generated when the proximal portion of the stabilization device limits at least one degree of movement between a superior vertebrae and an inferior vertebrae by contacting a surface of the superior vertebrae..

**[0016]** Another embodiment of the present invention also comprises a method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient. In this embodiment, a first countersink is formed in the inferior vertebrae. A distal end of a first stabilization device is advanced through the first counter sink and into a pedicle of the inferior vertebrae. A proximal portion of the first stabilization device is positioned such that the proximal portion lies at least partially within the first countersink and abuts against a surface of a first inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between a superior vertebrae and an inferior vertebrae. A second countersink is formed in the inferior vertebrae with substantially bilateral symmetry with respect to the first countersink. A distal end of a second stabilization device is advanced through the second counter sink and into a pedicle of the inferior vertebrae such that it is positioned with substantial bilateral symmetry with respect to the first stabilization device. A proximal portion of the second stabilization device is positioned at least partially within the second countersink such that the proximal portion abuts, with substantial bilateral symmetry with respect to the first stabilization device, against a surface of second inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

**[0017]** Another embodiment of the present invention comprises also comprises method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient. In this embodiment, a surface of a first inferior articular process of the superior adjacent vertebrae is modified. A distal end of a first stabilization device is advanced into a pedicle of the inferior vertebrae. A proximal portion of the first stabilization device is positioned such that the proximal portion abuts against the modified surface of the first inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between a superior vertebrae and an inferior vertebrae. A surface of a second inferior articular process of the superior adjacent vertebrae is modified. A distal end of a second stabilization device is advanced into a pedicle of the inferior vertebrae such that it is positioned with substantial bilateral symmetry with respect to the first stabilization device. A proximal portion of the second

stabilization device is positioned such that the proximal portion abuts, with substantial bilateral symmetry with respect to the first stabilization device, against the modified surface of second inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

**[0018]** Another embodiment of the present invention comprises a spinal stabilization device that includes an elongate body, having a proximal end and a distal end. A distal anchor is on the distal end of the elongate body. A retention structure is on the body, proximal to the distal anchor. A proximal anchor is moveably carried by the body. The proximal anchor has an outer surface, at least a portion of the outer surface being mechanically resilient. At least one complementary retention structure is on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

**[0019]** Yet another embodiment of the present invention comprises a spinal stabilization device that includes an elongate body, having a proximal end and a distal end. A distal anchor is on the distal end of the elongate body. A retention structure is on the body, proximal to the distal anchor. A proximal anchor is moveably carried by the body. The proximal anchor has an outer surface, at least a portion of the outer surface having an elastic modulus that is substantially similar to bone. At least one complementary retention structure on the proximal anchor is configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

**[0020]** Another embodiment of the present invention comprises a method limiting extension between an inferior and superior body structure of a spine. The method comprises inserting a stabilization into a patient from a lateral or anterior site and coupling a stabilization device only to the inferior body structure of the spine such that a portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

**[0021]** Another embodiment of the present invention also comprises a method of limiting at least one degree of movement a superior vertebrae and an inferior vertebrae of a patient. The method comprises providing a complementary interface on the superior adjacent vertebrae and advancing a distal end of a stabilization device into the inferior vertebrae; positioning a proximal portion of the stabilization device such that the

proximal portion abuts against the complementary interface to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

[0022] Another embodiment of the present invention comprises a spinal stabilization device that includes an elongate body, having a proximal end and a distal end, a distal anchor on the distal end of the elongate body and a proximal anchor carried to the body and having an outer surface that is radially adjustable with respect to the elongated body.

[0023] Another embodiment of the present invention comprises a spinal stabilization device that includes a body, having a proximal end and a distal end, a distal anchor on the distal end of the elongate body, a retention structure on the body, proximal to the distal anchor, and a proximal anchor, carried by the body, and having a diameter, the proximal anchor having means for adjusting the diameter of the proximal anchor.

[0024] Yet another embodiment of the present invention comprises a kit for spinal stabilization that comprises a spinal stabilization device and instructions for coupling the stabilization device only to an inferior body structure of the spine such that a portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

[0025] Another embodiment of the present invention comprises a kit for spinal stabilization that includes a spinal stabilization device comprising a distal end and a proximal end and instructions for inserting the distal end into an inferior vertebral body and positioning the proximal end of the device such that the device limits extension between the inferior vertebrae and a superior vertebrae body by contacting a surface of the superior vertebrae or an intermediate member coupled to the superior vertebrae.

#### Brief Description of the Drawings

[0026] FIG. 1A a side elevational view of a portion of a vertebra having an exemplary embodiment of a stabilization device implanted therein.

[0027] FIG. 1B is a posterior view of a portion of a vertebra having two devices similar to that of FIG. 1A implanted substantially bilaterally therein.

[0028] FIG. 1C is a posterior view of a portion of a vertebra having two devices similar to that of FIG. 1A implanted substantially bilaterally therein and a member extending between the two devices.

[0029] FIG. 1D is a side view of a portion of a vertebra with a guidewire inserted therein.

[0030] FIG. 1E is a side view of a portion of a vertebra as in FIG. 1D and a dilator in a compressed state.

[0031] FIG. 1F is a side view of a portion of a vertebra as in FIG. 1D and a dilator in an expanded state.

[0032] FIG. 2 is a side perspective view of the stabilization device of FIGS. 1A and 1B.

[0033] FIG. 3 is a side view of the stabilization device of FIG. 2.

[0034] FIG. 3A is a cross-sectional view of a body portion of the stabilization device of FIG. 2.

[0035] FIG. 4 is a partial cross-sectional view of a proximal portion of the stabilization device of FIG. 2.

[0036] FIG. 5 is an enlarged view of a portion of FIG. 4 labeled 5-5.

[0037] FIG. 6 is a side perspective view of a locking ring of the stabilization device of FIG. 3.

[0038] FIG. 7 is a side view of a modified embodiment of a body portion of the stabilization device shown in FIG. 2.

[0039] FIG. 7A is an enlarged view of a portion of FIG. 7 labeled 7A-7A.

[0040] FIG. 8 is a posterior view of a portion of a vertebra portions thereof removed to receive a fixation device.

[0041] FIG. 9A is a side view of a device configured to remove portions of a vertebra.

[0042] FIG. 9B is an enlarged side view of the distal end of the device of FIG. 9A.

[0043] FIG. 9C is a side view of a tool configured to insert a body of a stabilization device.

[0044] FIG. 9D is an enlarged side view of the tool of FIG. 9C.

[0045] FIG. 9E is an enlarged side view of the tool of FIG. 9C with a body of a stabilization device inserted therein.

[0046] FIG. 10A is a side view of another embodiment of a stabilization device.

[0047] FIG. 10B is a cross-sectional side view of the stabilization device of FIG. 10A.

[0048] FIGS. 11A and 11B are perspective rear and front views of another embodiment of a proximal anchor.

[0049] FIGS. 12A and 12B are perspective rear and front views of another embodiment of a proximal anchor. . .

[0050] FIGS. 13A and 13B are perspective rear and front views of another embodiment of a proximal anchor. . . .

[0051] FIG. 14 is a side view of another modified embodiment of the proximal anchor.

[0052] FIG. 15 is a side perspective view of another modified embodiment of the proximal anchor.

[0053] FIG. 16 is a side view of another modified embodiment of the proximal anchor.

[0054] FIG. 17 is a side perspective view of an embodiment of an insertion tool configured to insert a proximal onto a body portion of a fixation device.

[0055] FIG. 18 is a cross-sectional side view of the insertion tool of FIG. 17.

[0056] FIG. 19 is a cross-sectional side view of a modified embodiment of a stabilization device.

[0057] FIG. 20A is a cross-sectional side view of a modified embodiment of a stabilization device in a un-expanded configuration.

[0058] FIG. 20B is a cross-sectional side view of a modified embodiment of a stabilization device in an expanded configuration.

[0059] FIG. 20C is a closer cross-sectional side view of the embodiment of FIG. 20A in a un-expanded configuration.

[0060] FIG. 20D is a closer cross-sectional side view of the embodiment of FIG. 20B in an expanded configuration

[0061] FIG. 21 is a cross-sectional side view of a modified embodiment of a stabilization device in an expanded configuration.

[0062] FIG. 22 is a cross-sectional side view of another modified embodiment of a stabilization device in an expanded configuration.

Detailed Description of the Preferred Embodiments

**[0063]** Although the stabilization devices of the present invention will be disclosed primarily in the context of a spinal stabilization procedure, the methods and structures disclosed herein are intended for application in any of a variety medical applications, as will be apparent to those of skill in the art in view of the disclosure herein. For example, certain features and aspects of bone stabilization device and techniques described herein may be applicable to proximal fractures of the femur and a wide variety of fractures and osteotomies, the hand, such as interphalangeal and metacarpophalangeal arthrodesis, transverse phalangeal and metacarpal fracture fixation, spiral phalangeal and metacarpal fracture fixation, oblique phalangeal and metacarpal fracture fixation, intercondylar phalangeal and metacarpal fracture fixation, phalangeal and metacarpal osteotomy fixation as well as others known in the art. See e.g., U.S. Patent No. 6,511,481, which is hereby incorporated by reference herein. A wide variety of phalangeal and metatarsal osteotomies and fractures of the foot may also be stabilized using the bone fixation devices described herein. These include, among others, distal metaphyseal osteotomies such as those described by Austin and Reverdin-Laird, base wedge osteotomies, oblique diaphyseal, digital arthrodesis as well as a wide variety of others that will be known to those of skill in the art. Fractures of the fibular and tibial malleoli, pilon fractures and other fractures of the bones of the leg may be fixated and stabilized with these bone fixation devices with or without the use of plates, both absorbable or non-absorbing types, and with alternate embodiments of the current invention. The stabilization devices may also be used to attach tissue or structure to the bone, such as in ligament reattachment and other soft tissue attachment procedures. Plates and washers, with or without tissue spikes for soft tissue attachment, and other implants may also be attached to bone, using either resorbable or nonresorbable fixation devices depending upon the implant and procedure. The stabilization devices may also be used to attach sutures to the bone, such as in any of a variety of tissue suspension procedures. The bone stabilization device described herein may be used with or without plate(s) or washer(s), all of which can be either permanent, absorbable, or combinations.

**[0064]** FIGS. 1A and 1B are side and rear elevational views of a pair of bone stabilization devices 12, positioned within a body structure 10a of the spine. As will be explained in detail below, the bone stabilization device 12 may be used in a variety of techniques to stabilize the spine. In one embodiment, the device 12 is attached (e.g.,

inserted or screwed into) and/or coupled to a single body structure and limits motion of a second body structure. In the another embodiment, the device 12 limits extension in the spine by being attached and/or coupled to an inferior body structure and limiting motion of an adjacent superior body structure. "Body structure" as used herein is the anterior solid segment and the posterior segment of any vertebrae of the five regions (cervical, thoracic, lumbar, sacral, and coccygeal) of the spine. In some embodiments, the device limits motion by contacting, abutting against and/or wedging against the adjacent body structure and/or a device coupled to the adjacent body structure.

**[0065]** With reference to the illustrated embodiment of FIGS. 1A and 1B, the distal end of the bone stabilization device 12 is inserted into the pedicle of the inferior vertebrae, preferably through the pars (i.e., the region between the lamina between and the superior articular processes). The proximal end of the device 12 extends above the pars such that it limits motion of a superior adjacent vertebrae 10b with respect to the inferior adjacent vertebrae 10b. In one embodiment, the proximal end of the device limits motion by abutting and/or wedging against a surface of the superior adjacent vertebrae as the superior adjacent vertebrae moves relative to the inferior adjacent vertebrae. In this manner, at least one degree of motion between the inferior and superior vertebrae may be limited. For example, the spine generally has six (6) degrees of motion which include flexion, extension, left and right lateral bending and axial rotation or torsion. In the illustrated embodiment, at least extension of the spine is limited. Embodiments in which the devices are inserted with bilateral symmetry can be used to limit left and right lateral bending.

**[0066]** In the illustrated embodiment, motion of the spine is limited when the proximal end of the device contacts, abuts, and/or wedges against the inferior articular process of the superior adjacent vertebra 10b. In this application, it should be appreciated that one or more intermediate member(s) (e.g., plates, platforms, coatings, cement, and/or adhesives) can be coupled to the superior adjacent vertebra 10b or other portions of the spine that the device contacts, abuts, and/or wedges against. Thus, in this application, when reference is made to the device contacting, abutting and/or wedging against a portion of the spine it should be appreciated that this includes embodiments in which the device contacts, abuts and/or wedges against one or more intermediate members that are coupled to the spine unless otherwise noted.

**[0067]** As explained below, the bone stabilization devices 12 may be used after laminectomy, discectomy, artificial disc replacement, microdiscectomy, laminotomy and other applications for providing temporary or permanent stability in the spinal column. For example, lateral or central spinal stenosis may be treated with the bone fixation devices 12 and techniques described below. In such procedures, the bone fixation devices 12 and techniques may be used alone or in combination with laminectomy, discectomy, artificial disc replacement, and/or other applications for relieving pain and/or providing stability.

**[0068]** An embodiment of the stabilization device 12 will now be described in detail with initial reference to FIGS. 2-4. The stabilization device 12 comprises a body 28 that extends between a proximal end 30 and a distal end 32. The length, diameter and construction materials of the body 28 can be varied, depending upon the intended clinical application. In embodiments optimized for spinal stabilization in an adult human population, the body 28 will generally be within the range of from about 20-90 mm in length and within the range of from about 3.0-8.5 mm in maximum diameter. The length of the helical anchor, discussed below, may be about 8-80 millimeters. Of course, it is understood that these dimensions are illustrative and that they may be varied as required for a particular patient or procedure.

**[0069]** In one embodiment, the body 28 comprises titanium. However, as will be described in more detail below, other metals, or bioabsorbable or nonabsorbable polymeric materials may be utilized, depending upon the dimensions and desired structural integrity of the finished stabilization device 12.

**[0070]** The distal end 32 of the body 28 is provided with a cancellous bone anchor and/or distal cortical bone anchor 34. Generally, for spinal stabilization, the distal bone anchor 34 is adapted to be rotationally inserted into a portion (e.g., the pars or pedicle) of a first vertebra. In the illustrated embodiment, the distal anchor 34 comprises a helical locking structure 72 for engaging cancellous and/or distal cortical bone. In the illustrated embodiment, the locking structure 72 comprises a flange that is wrapped around a central core 73, which in the illustrated embodiment is generally cylindrical in shape. The flange 72 extends through at least one and generally from about two to about 50 or more full revolutions depending upon the axial length of the distal anchor 34 and intended application. The flange will generally complete from about 2 to about 60 revolutions. The helical flange 72 is preferably provided with a pitch and an axial spacing

to optimize the retention force within cancellous bone. While the helical locking structure 72 is generally preferred for the distal anchor, it should be appreciated that other distal anchor could comprises other structures configured to secure the device in the cancellous bone anchor and/or distal cortical bone, such as, for example, various combinations and sub-combinations of hooks, prongs, expandable flanges, etc. See also e.g., U.S. Patent No. 6,648,890, the entirety of which is hereby incorporated by reference herein.

**[0071]** The helical flange 72 of the illustrated embodiment has a generally triangular cross-sectional shape (see FIG. 3A). However, it should be appreciated that the helical flange 72 can have any of a variety of cross sectional shapes, such as rectangular, oval or other as deemed desirable for a particular application through routine experimentation in view of the disclosure herein. For example, in one modified embodiment, the flange 72 has a triangular cross-sectional shape with a blunted or square apex. One particularly advantageous cross-sectional shape of the flange are the blunted or square type shapes. Such shapes can reduce cutting into the bone as the proximal end of the device is activated against causing a windshield wiper effect that can loosen the device 12. The outer edge of the helical flange 72 defines an outer boundary. The ratio of the diameter of the outer boundary to the diameter of the central core 73 can be optimized with respect to the desired retention force within the cancellous bone and giving due consideration to the structural integrity and strength of the distal anchor 34. Another aspect of the distal anchor 34 that can be optimized is the shape of the outer boundary and the central core 73, which in the illustrated embodiment are generally cylindrical.

**[0072]** The distal end 32 and/or the outer edges of the helical flange 72 may be atraumatic (e.g., blunt or soft). This inhibits the tendency of the stabilization device 12 to migrate anatomically distally and potentially out of the vertebrae after implantation. Distal migration is also inhibited by the dimensions and presence of a proximal anchor 50, which will be described below. In the spinal column, distal migration is particularly disadvantageous because the distal anchor 34 may harm the tissue, nerves, blood vessels and/or spinal cord which lie within and/or surround the spine. Such features also reduce the tendency of the distal anchor to cut into the bone during the "window-wiper effect" that is caused by cyclic loading of the device as will be described. In other embodiments, the distal end 32 and/or the outer edges of the helical flange 72 may be sharp and/or configured such that the distal anchor 34 is self tapping and/or self drilling.

[0073] A variety of other embodiments for the distal anchor 32 can also be used. For example, the various distal anchors described in co-pending U.S. Patent Application No. 10/012,687, filed November 13, 2001 can be incorporated into the stabilization device 12 described herein. The entire contents of this application are hereby expressly incorporated by reference. In particular, the distal anchor 32 may comprise a single helical thread surrounding a lumen, much as in a conventional corkscrew. Alternatively, a double helical thread may be utilized, with the distal end of the first thread rotationally offset from the distal end of the second thread. The use of a double helical thread can enable a greater axial travel for a given degree of rotation and greater retention force than a corresponding single helical thread. Specific distal anchor designs can be optimized for the intended use, taking into account desired performance characteristics, the integrity of the distal bone, and whether the distal anchor is intended to engage exclusively cancellous bone or will also engage cortical bone. In still other embodiments, the distal anchor 34 may be formed without a helical flange. For example, various embodiments of levers, prongs, hooks and/or radially expandable devices may also be used. See e.g., U.S. Patent No. 6,648,890, which is hereby expressly incorporated by reference in its entirety.

[0074] As shown in FIG. 3A, the body 28 is cannulated forming a central lumen 42 to accommodate installation over a placement wire as is understood in the art. The cross section of the illustrated central lumen is circular but in other embodiments may be non circular, e.g., hexagonal, to accommodate a corresponding male tool for installation or removal of the body 28 as explained below. In other embodiments, the body 28 may partially or wholly solid.

[0075] With continued reference to FIGS. 2-4, the proximal end 30 of the body 28 is provided with a rotational coupling 70, for allowing the body 28 to be rotated. Rotation of the rotational coupling 70 can be utilized to rotationally drive the distal anchor 32 into the bone. In such embodiments, any of a variety of rotation devices may be utilized, such as electric drills or hand tools, which allow the clinician to manually rotate the proximal end 30 of the body 28. Thus, the rotational coupling 70 may have any of a variety of cross sectional configurations, such as one or more curved faces, flats or splines. In the illustrated embodiment, the rotational coupling 70 is a male element in the form of a hexagonal projection. However, in other embodiments, the rotational coupling 70 may be in the form of a female component, machined, milled or attached to the

proximal end 30 of the body 28. For example, in one such embodiment, the rotational coupling 70 comprises an axial recess with a polygonal cross section, such as a hexagonal cross section. As explained above, the axial recess may be provided as part of the central lumen 42.

**[0076]** The proximal end 30 of the fixation device is also provided with a proximal anchor 50. The proximal anchor 50 comprises a housing 52, which forms a lumen 53 (see FIG. 5) configured such that the body 28 may extend, at least partially, through the proximal anchor 50. The proximal anchor 50 is axially distally moveable along the body 28 such that the proximal anchor 50 can be properly placed with respect the inferior vertebral and superior vertebra. As will be explained below, complimentary locking structures such as threads, levers, split rings, and/or ratchet like structures between the proximal anchor 50 and the body 28 resist proximal movement of the anchor 50 with respect to the body 28 under normal use conditions. The proximal anchor 50 preferably can be axially advanced along the body 28 with and/or without rotation as will be apparent from the disclosure herein.

**[0077]** With particular reference to FIGS. 4-6, in the illustrated embodiment, the complementary structure of the proximal anchor 50 is formed by an annular ring 51, which is positioned within an annular recess 55 formed along the lumen 53. As will be explained below, the ring 51 comprises surface structures 54 which interact with complimentary surface structures 58 on the body 28. In the illustrated embodiment, the complimentary surface structures 58 comprise a series of annular ridges or grooves 60 formed on the surface of the body 28. The surface structures 54 and complementary surface structures 58 permit distal axial travel of the proximal anchor 50 with respect to the body 28, but resist proximal travel of the proximal anchor 50 with respect to the body 28 as explained below.

**[0078]** As shown in FIG. 6, the annular ring 51 is split (i.e., has a least one gap) and is interposed between the body 28 and the recess 55 of the proximal anchor 50 (see FIG. 5). In the illustrated embodiment, the ring 51 comprises a tubular housing 57 (see FIG. 6), which defines a gap or space 59. In one embodiment, the gap 59 is defined by a pair of edges 61a, 61b, that are generally straight and parallel to each other. Although not illustrated, it should be appreciated that in modified embodiments, the ring 51 can be formed without a gap. When the ring 51 is positioned along the body 28, the ring 51 preferably surrounds a substantial portion of the body 28. The ring 51 can be

configured so that the ring 51 can flex or move radially outwardly in response to an axial force so that the ring 51 can be moved relative to the body 28, as described below.

**[0079]** In the illustrated embodiment, the tubular housing 57 includes at least one and in the illustrated embodiment ten teeth or flanges 63, which are configured to engage the complementary surface structures 58 on the body 28 in a ratchet-like motion. In the illustrated embodiment (see FIG. 5), the teeth or flanges include a first surface 65 that lies generally perpendicular to the longitudinal axis of the anchor and generally faces the proximal direction (i.e., the direction labeled "P" in FIG. 5) and a second surface 67 that is inclined with respect to the longitudinal axis of the anchor and that faces distal direction (i.e., the direction labeled "D" in FIG. 5). It should be noted that the proximal and directions in FIG. 5 are reversed with respect to FIG. 4.

**[0080]** With continued reference to FIG. 5, the recess 55 is sized and dimensioned such that as the proximal anchor 50 is advanced distally over the body, the second surface 67 of the annular ring 51 can slide along and over the complementary retention structures 58 of the body 28. That is, the recess 55 provides a space for the annular ring to move radially away from the body 28 as the proximal anchor 50 is advanced distally.

**[0081]** A distal portion 69 of the recess 55 is sized and dimensioned such that after the proximal anchor 50 is appropriately advanced, proximal motion of the proximal anchor 50 is resisted as the annular ring 51 becomes wedged between the body 28 and an angled engagement surface 71 of the distal portion 69. In this manner, proximal movement of the proximal anchor 50 under normal use conditions may be prevented. In modified embodiments, the annular ring 51 can be sized and dimensioned such that the ring 51 is biased inwardly to engage the retention structures 58 on the body 28. The bias of the annular ring 51 can result in a more effective engagement between the complementary retention structures 58 of the body and the retention structures 54 of the ring 51.

**[0082]** In certain embodiments, it is advantageous for the outer surface 49 of the proximal anchor 50 to rotate with respect to the body 28. This arrangement advantageously reduces the tendency of the body 28 to rotate and/or move within the superior articular process of the inferior vertebrae 10a as the outer surface 49 contacts, abuts or wedges against the inferior articular process of the superior vertebrae 10b. In the illustrated embodiment, rotation of the outer surface 49 is provided by configuring the

lumen 53 and annular recess 55 such that the anchor 50 can rotate about the body 28 and ring 51. Preferably, as the anchor 50 rotates the axial position of the anchor 50 with respect to the body 28 remains fixed. That is, the annular ring 51 resists proximal travel of the proximal anchor 50 with respect to the body 28 while the anchor 50 is permitted to rotate about the body 28 and ring 51. Of course those of skill in the art will recognize other configurations and mechanisms (e.g., bearings, rollers, slip rings, etc.) for providing rotation of the outer surface 49 with respect to the body 28. In a modified embodiment, the proximal anchor 50 can be configured such that it does not rotate with respect to the body 28. In such an embodiment, a key or one or more anti-rotational features (e.g., splines, grooves, flat sides, etc.) can be provided between the proximal anchor 50, the ring 51 and/or the body 51 to limit or prevent rotation of the proximal anchor 50 with respect to the body 28.

**[0083]** As mentioned above, it is contemplated that various other retention structures 54 and complementary retention structures 58 may be used between the body 28 and the proximal anchor 50 to permit distal axial travel of the proximal anchor 50 with respect to the body 28, but resist proximal travel of the proximal anchor 50 with respect to the body 28. Examples of such structures can be found in U.S. Patent No. 6,685,706, entitled "PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM." The entire contents of this patent is hereby expressly incorporated by reference herein. In such embodiments, the structures 54 and complementary retention structures 58 can be configured to allow the proximal anchor to be advanced with or without rotation with respect to the body 28.

**[0084]** As mentioned above, the complimentary surface structures 58 on the body 28 comprise threads, and/or a series of annular ridges or grooves 60. These retention structures 58 are spaced axially apart along the body 28, between a proximal limit 62 and a distal limit 64. See FIG. 4. The axial distance between proximal limit 62 and distal limit 64 is related to the desired axial working range of the proximal anchor 50, and thus the range of functional sizes of the stabilization device 12. Thus, the stabilization device 12 of the example embodiment can provide accurate placement between the distal anchor 34 and the proximal anchor 50 throughout a range of motion following the placement of the distal anchor in a vertebra. That is, the distal anchor 34 may be positioned within the cancellous and/or distal cortical bone of a vertebra, and the proximal anchor may be distally advanced with respect to the distal anchor throughout a

range to provide accurate placement of the proximal anchor 50 with respect to the vertebra without needing to relocate the distal anchor 34 and without needing to initially locate the distal anchor 34 in a precise position with respect to the proximal side of the bone or another vertebra. The arrangement also allows the compression between the distal anchor 34 and the proximal anchor 50 to be adjusted. Providing a working range throughout which positioning of the proximal anchor 50 is independent from setting the distal anchor 34 allows a single device to be useful for a wide variety of different anatomies, as well as eliminates or reduces the need for accurate device measurement. In addition, this arrangement allows the clinician to adjust the compression force during the procedure without adjusting the position of the distal anchor. In this manner, the clinician may focus on positioning the distal anchor sufficiently within the vertebra to avoid or reduce the potential for distal migration out of the vertebra, which may damage the particularly delicate tissue, blood vessels, nerves and/or spinal cord surrounding or within the spinal column. In addition or alternative, the above described arrangement allows the clinician to adjust the positioning of the proximal anchor 50 with respect to the inferior articular process of the superior adjacent vertebrae. In this manner, the clinician may adjust the position of the proximal anchor 50 without adjusting the position of the distal anchor such that the anchor 50 is configured to wedge or abut against inferior articular process of the superior adjacent vertebrae. In a modified embodiment, the position of the proximal anchor 50 with respect to the surrounding vertebra can be adjusted by rotating the device 12 and advancing the distal anchor and the proximal anchor carried by the body.

**[0085]** In the embodiment of FIGS. 4-6, the proximal anchor 50 can be distally advanced over the body 28 without rotating the proximal anchor 50 with respect to the body 28. In one embodiment, the ring 51 and the proximal anchor 50 are rotationally linked by, for example, providing inter-engaging structures (e.g., tabs, ridges and the like). In such an embodiment, the proximal anchor 50 can be advanced without rotating the proximal anchor 50 and be removed and/or the position adjusted in a proximal or distal direction by rotating the proximal anchor with respect to the body 28. This can allow the surgeon to remove an proximal anchor and use a different sized or configured proximal anchor 50 if the first proximal anchor is determined to be inadequate. In such an embodiment, the proximal anchor 50 is preferably provided with one or more engagement structures (e.g., slots, hexes, recesses, protrusions, etc.) configured to engage a rotational

and/or gripping device (e.g., slots, hexes, recesses, protrusions, etc.). Thus, in some embodiments, the proximal anchor 50 can be pulled and/or rotated such that the anchor 50 is removed from the body.

**[0086]** In many applications, the working range is at least about 10% of the overall length of the device, and may be as much as 20% or 50% or more of the overall device length. In the context of a spinal application, working ranges of up to about 10 mm or more may be provided, since estimates within that range can normally be readily accomplished within the clinical setting. The embodiments disclosed herein can be scaled to have a greater or a lesser working range, as will be apparent to those of skill in the art in view of the disclosure herein.

**[0087]** In embodiments optimized for spinal stabilization in an adult human population, the anchor 50 will have a diameter within the range of from about 1 to 1/16 of an inch in another embodiment the proximal anchor proximal anchor 50 within the range from about .5 to 1/8 of an inch in another embodiment.

**[0088]** With reference back to FIGS. 2-4, in the illustrated embodiment, the outer surface 49 of the proximal anchor 50 has a smooth or spherical shape. As will be explained below, the outer surface 49 of the proximal anchor 50 is configured to abut against the inferior facet of the superior adjacent vertebrae. In this manner, motion between the adjacent vertebrae may be limited and/or constrained.

**[0089]** FIG. 7 illustrates an embodiment in which the body 28 comprises a first portion 36 and a second portion 38 that are coupled together at a junction 40. In the illustrated embodiment, the first portion 36 carries the distal anchor 34 (shown without a central core) while the second portion 38 forms the proximal end 30 of the body 28. As will be explained in more detail below, in certain embodiments, the second portion 38 may be used to pull the body 28 and therefore will sometimes be referred to as a "pull-pin." The first and second portions 36, 38 are preferably detachably coupled to each other at the junction 40. In the illustrated embodiment, the first and second portions 36, 38 are detachably coupled to each other via interlocking threads. Specifically, as best seen in FIG. 7A, the body 28 includes an inner surface 41, which defines a central lumen 42 that preferably extends from the proximal end 30 to the distal end 32 throughout the body 28. At the proximal end of the first portion 36, the inner surface 41 includes a first threaded portion 44. The first threaded portion 44 is configured to mate with a second threaded portion 46, which is located on the outer surface 45 of the second portion 38. The

interlocking annular threads of the first and second threaded portions 44, 46 allow the first and second portions 36, 38 to be detachably coupled to each other. In one modified embodiment, the orientation of the first and second threaded portions 44, 46 can be reversed. That is, the first threaded portion 44 can be located on the outer surface of the first portion 36 and the second threaded portion 46 can be located on the inner surface 41 at the distal end of the second portion 38. Any of a variety of other releasable complementary engagement structures may also be used, to allow removal of second portion 38 following implantation, as is discussed below.

**[0090]** In a modified arrangement, the second portion 38 can comprise any of a variety of tensioning elements for permitting proximal tension to be placed on the distal anchor 34 while the proximal anchor is advanced distally to compress the fracture. For example, any of a variety of tubes or wires can be removably attached to the first portion 36 and extend proximally to the proximal handpiece. In one such arrangement, the first portion 36 can include a releasable connector in the form of a latching element, such as an eye or hook. The second portion 38 can include a complementary releasable connector (e.g., a complementary hook) for engaging the first portion 36. In this manner, the second portion 38 can be detachably coupled to the first portion 36 such proximal traction can be applied to the first portion 36 through the second portion as will be explained below. Alternatively, the second portion 48 may be provided with an eye or hook, or transverse bar, around which or through which a suture or wire may be advanced, both ends of which are retained at the proximal end of the device. Following proximal tension on the tensioning element during the compression and/or positioning step, one end of the suture or wire is released, and the other end may be pulled free of the device. Alternate releasable proximal tensioning structures may be devised by those of skill in the art in view of the disclosure herein.

**[0091]** In a final position, the distal end of the proximal anchor 50 preferably extends distally past the junction 40 between the first portion 36 and the second portion 38. As explained above, the proximal anchor 50 is provided with one or more surface structures 54 for cooperating with complementary surface structures 58 on the first portion 36 of the body 28.

**[0092]** In this embodiment, the stabilization device 12 may include an antirotation lock (not shown) between the first portion 36 of the body 28 and the proximal collar 50. For example, the first portion 36 may include one or more of flat sides (not

shown), which interact with corresponding flat structures in the proximal collar 50. As such, rotation of the proximal collar 50 is transmitted to the first portion 36 and distal anchor 34 of the body 28. Of course, those of skill in the art will recognize various other types of splines or other interfit structures can be used to prevent relative rotation of the proximal anchor and the first portion 36 of the body 28. To rotate the proximal anchor 50, the housing 52 may be provided with a gripping structure (not shown) to permit an insertion tool to rotate the flange proximal anchor 50. Any of a variety of gripping structures may be provided, such as one or more slots, recesses, protrusions, flats, bores or the like. In one embodiment, the proximal end of the proximal anchor 50 is provided with a polygonal, and, in particular, a pentagonal or hexagonal recess or protrusion.

**[0093]** Methods implanting stabilization devices described above as part of a spinal stabilization procedure will now be described. Although certain aspects and features of the methods and instruments described herein can be utilized in an open surgical procedure, the disclosed methods and instruments are optimized in the context of a percutaneous or minimally invasive approach in which the procedure is done through one or more percutaneous small openings. Thus, the method steps which follow and those disclosed are intended for use in a trans-tissue approach. However, to simplify the illustrations, the soft tissue adjacent the treatment site have not been illustrated in the drawings.

**[0094]** In one embodiment of use, a patient with a spinal instability is identified. The patient is preferably positioned face down on an operating table, placing the spinal column into a normal or flexed position. A trocar optionally may then be inserted through a tissue tract and advanced towards a first vertebrae. In another embodiment, biopsy needle (e.g., Jamshidi™) device can be used. A guidewire may then be advanced through the trocar (or directly through the tissue, for example, in an open surgical procedure) and into the first vertebrae. With reference to FIG. 1D, the guide wire 110 is preferably inserted into the pedicle of the vertebrae preferably through the pars (i.e. the region of the lamina between the superior and inferior articular processes). With reference to FIG. 1E, a suitable expandable access sheath or dilator 112 can then be inserted over the guidewire and expanded (FIG. 1F) to enlarge the tissue tract and provide an access lumen for performing the methods described below in a minimally invasive manner. In a modified embodiment, a suitable tissue expander (e.g., a balloon expanded catheter or a series of radially enlarged sheaths) can be inserted over the guidewire and

expanded to enlarge the tissue tract. A surgical sheath can then be advanced over the expanded tissue expander. The tissue expander can then be removed such that the surgical sheath provides an enlarged access lumen. Any of a variety of expandable access sheaths or tissue expanders can be used, such as, for example, a balloon expanded catheter, a series of radially enlarged sheaths inserted over each other, and/or the dilation introducer described in U.S. Patent Application No. 11/038,784, filed January 19, 2005 (Publication No. 2005/0256525), the entirety of which is hereby incorporated by reference herein.

**[0095]** A drill with a rotatable tip may be advanced over the guidewire and through the sheath. The drill may be used to drill an opening in the vertebrae. The opening may be configured for (i) for insertion of the body 28 of the bone stabilization device 12, (ii) taping and/or (iii) providing a counter sink for the proximal anchor 50. In other embodiments, the step of drilling may be omitted. In such embodiments, the distal anchor 34 is preferably self-tapping and self drilling. In embodiments, in which an opening is formed, a wire or other instrument may be inserted into the opening and used to measure the desired length of the body 29 of the device 12.

**[0096]** The body 28 of the fixation device may be advanced over the guidewire and through the sheath until it engages the vertebrae. The body 28 may be coupled to a suitable insertion tool prior to the step of engaging the fixation device 12 with the vertebrae. The insertion tool may be configured to engage the coupling 70 on the proximal end of the body 28 such that insertion tool may be used to rotate the body 28. In such an embodiment, the fixation device 12 is preferably configured such that it can also be advanced over the guidewire.

**[0097]** The insertion tool may be used to rotate the body 28 thereby driving the distal anchor 34 to the desired depth within the pedicle of the vertebrae. The proximal anchor 50 may be carried by the fixation device prior to advancing the body 28 into the vertebrae, or may be attached and/or coupled to the body 28 following placement (partially or fully) of the body 28 within the vertebrae. In another embodiment, the anchor 50 may be pre-attached and/or coupled to the body 28.

**[0098]** In one embodiment, the clinician will have access to an array of devices 12, having, for example, different diameters, axial lengths, configurations and/or shapes. The clinician will assess the position of the body 28 with respect to the superior vertebrae and chose the device 12 from the array, which best fits the patient anatomy to

achieve the desired clinical result. In another embodiment, the clinician will have access to an array of devices 12, having, for example, bodies 28 of different diameters, axial lengths. The clinician will also have an array of proximal anchors 50, having, for example, different configurations and/or shapes. The clinician will choose the appropriate body 28 and then assess the position of the body 28 with respect to the superior vertebrae and chose the proximal anchor 50 from the array, which best fits the patient anatomy to achieve the desired clinical result. In such an embodiment, the proximal anchor 50 is advantageously coupled to body 28 after the body 28 is partially or fully inserted into the vertebrae.

**[0099]** Once the distal anchor 34 is in the desired location, the proximal anchor 50 is preferably advanced over the body 28 until it reaches its desired position. This may be accomplished by pushing on the proximal anchor 50 or by applying a distal force to the proximal anchor 50. In another embodiment, the proximal anchor 50 is advanced by applying a proximal retraction force to the proximal end 30 of body 28, such as by conventional hemostats, pliers or a calibrated loading device, while distal force is applied to the proximal anchor 50. In this manner, the proximal anchor 50 is advanced distally with respect to the body 28 until the proximal anchor 50 is in its proper position (e.g., positioned snugly against the outer surface of the vertebra.) Appropriate tensioning of the stabilization device 12 can be accomplished by tactile feedback or through the use of a calibration device for applying a predetermined load on the stabilization device 12. As explained above, one advantage of the structure of the illustrated embodiments is the ability to adjust the compression and/or the position of the proximal anchor 50 independently of the setting of the distal anchor 34 within the vertebra. For example, the positioning of the distal anchor 34 within the vertebra can be decoupled from the positioning of the proximal anchor 50 with respect to the superior vertebra.

**[0100]** In one embodiment, the proximal anchor 50 is pushed over the body 28 by tapping the device with a slap hammer or similar device that can be used over a guidewire. In this manner, the distal end of the device 12 is advantageously minimally disturbed, which prevents (or minimizes) the threads in the bore from being stripped.

**[0101]** Following appropriate tensioning of the proximal anchor 50, the proximal portion of the body 28 extending proximally from the proximal anchor 50 can be removed. In one embodiment, this may involve cutting the proximal end of the body 28. For example, the proximal end of the body may be separated by a cutting instrument

or by cauterizing. Cauterizing may fuse the proximal anchor 50 to the body 32 thereby adding to the retention force between the proximal anchor 50 and the body 28. Such fusion between the proximal anchor and the body may be particularly advantageous if the pin and the proximal anchor are made from a polymeric or plastic material. In this manner, as the material of the proximal anchor and/or the pin is absorbed or degrades, the fusion caused by the cauterizing continues to provide retention force between the proximal anchor and the body. In another embodiment, the body comprises a first and a second portion 36, 38 as described above. In such an embodiment, the second portion 38 may detached from the first portion 36 and removed. In the illustrated embodiment, this involves rotating the second portion 38 with respect to the first portion via the coupling 70. In still other embodiments, the proximal end of the body 28 may remain attached to the body 28.

**[0102]** The access site may be closed and dressed in accordance with conventional wound closure techniques and the steps described above may be repeated on the other side of the vertebrae for substantial bilateral symmetry as shown in FIGS. 1A and 1B. The bone stabilization devices 12 may be used alone or in combination with other surgical procedures such as laminectomy, discectomy, artificial disc replacement, and/or other applications for relieving pain and/or providing stability.

**[0103]** As will be explained below, the superior body structure (e.g., superior vertebrae the superior vertebrae 10b) can be conformed to the device by providing a complementary surface or interface. In one embodiment, the superior vertebrae can be modified using a separate drill or reamer that is also used to form the countersink 300 described above. In other embodiments, the drill that is used to form an opening in the inferior superior body can be provided with a countersink portion that is also used to modify the shape of the superior vertebrae 10b. In still other embodiments, the shape of the superior vertebrae 10b can be modified using files, burrs and other bone cutting or resurfacing devices to form a complementary surface or interface for the proximal anchor 50.

**[0104]** As mentioned above, a countersink can be provided for the proximal anchor 50. With reference to FIG. 8, a pair of counter sinks 300 are shown formed in or near the pars of the inferior vertebrae 10a. Each counter sink 300 is preferably configured to generally correspond to a distal facing portion 49a (see FIG. 4 or FIG. 10A) of the proximal anchor 50. In this manner, the proximal anchor 50, in a final position, may be seated at least partially within the inferior vertebrae 10a. In the illustrated embodiment,

the countersink 300 has a generally spherical configuration that corresponds generally to the spherical shape of the distal portion 49a of the proximal anchor 50 of the illustrated embodiment. In modified embodiments, the countersink 300 can have a modified shape (e.g., generally cylindrical, conical, rectangular, etc.) and/or generally configured to correspond to the distal portion of a proximal anchor 50 with a different shape than the proximal anchor illustrated in FIGS. 2-4.

**[0105]** The countersink 300 advantageously disperses the forces received by the proximal anchor 50 by the superior vertebrae 10b and transmits said forces to the inferior vertebrae 10a. As will be explained in more detail below, the countersink 300 can be formed by a separate drilling instrument or by providing a counter sink portion on a surgical drill used to form a opening in the body 10b.

**[0106]** In addition or in the alternative to creating the countersink 300, the shape of the inferior articular process IAP (which can include the facet in certain embodiments) of the superior vertebrae 10b may be modified in order to also disperse the forces generated by the proximal anchor 50 contacting, abutting and/or wedging against the superior vertebrae 10b. For example, as shown in FIG. 8, a portion 304 of the inferior articular process IAP of the superior vertebrae 10b that generally faces the proximal anchor 50 can be removed with the goal of dispersing and/or reducing the forces applied to the proximal anchor 50. In the illustrated embodiment, the inferior articular process is provided with a generally rounded recess 306 that corresponds generally to the rounded outer surface 49 of the proximal anchor 50. In modified embodiments, the inferior articular process IAP can be formed into other shapes in light of the general goal to reduce and/or disperse the forces applied to the proximal anchor 50. For example, in certain embodiments, the inferior articular process IAP may be formed into a generally flat, blunt or curved shape. In other embodiments, the inferior articular process IAP may be configured to abut and/or wedge more efficiently with a proximal anchor 50 of a different shape (e.g., square, oval, etc.). In general, the countersink 300 and surface 306 provided for an increased contact surface between the superior vertebra and the proximal anchor 50 and the inferior vertebra and the proximal anchor 50. This contact area reduces stress risers in the device and the associated contact areas of the vertebrae. In addition, the windshield wiper affect is reduced as the forces transmitted to the proximal anchor 50 from the superior vertebrae are transmitted through the area formed by the countersink 300.

**[0107]** FIGS. 9A and 9B illustrate an exemplary embodiment of a device 310 that can be used to form the countersink 300 and/or the recess 306 described above. As shown, the device comprises a body 312 having a distal end 314, a proximal end 316 and a guidewire lumen (not shown) extending therethrough. The proximal end 316 is configured to engage any of a variety of standard driving tools as is known in the art. The distal end 314 is provided with an outer surface 320 that generally corresponds to the outer surface 49 of the proximal anchor 50. The outer surface 320 is also provided with one or more removal or cutting features 318 (e.g., flutes, sharp edges, etc.) so as to remove or cut bone as the device 310 is rotated. A pin 321 (shown in dashed lines in FIG. 9B) can be provided at the end of the device 310. The pin 321 can be inserted into the hole formed in the vertebrae and helps to center and support the device 321 at it cuts the countersink 300 and/or recess 306 into the bone.

**[0108]** In use, the device 310 is advanced over a guidewire that is inserted into the inferior vertebrae 10b. As the device 310 is advanced and rotated, the device 310 encounters the inferior process IAP (see FIG. 8) of the superior vertebrae 10b and portions thereof are removed. Further advancement of the device 310, forms the countersink 300 in the superior process of the inferior vertebrae 10a and removes additional portions of the superior vertebrae 10b. Accordingly, in this embodiment, the device 310 can be used to form both the countersink 300 and to change the shape of the inferior articular process IAP of the superior vertebrae 10b.

**[0109]** FIGS. 9C-E illustrate an insertion tool 600 that may be used to rotate and insert the body 29 as described above. As shown, the tool 600 generally comprises an elongated shaft 602 having a distal end 604, a proximal end 606 and a guidewire lumen 608 extending there through. In the illustrated embodiment, the proximal end 604 includes a flat edge 610 and engagement feature 612 for engaging a driving tool (e.g., a drill). In modified embodiments, the proximal end 606 can include a handle such that the tool 600 can be rotated manually.

**[0110]** The distal end 604 of the tool 606 is provided with an distal sleeve portion 614 which has an outer shape that preferably corresponds substantially to the outer surface shape of the proximal anchor used in the procedure. Within the distal sleeve portion 614 is a lumen 616, which communicates with the guidewire lumen 608 and is configured to receive the proximal end of the body 28. The lumen 616 includes a rotational region 618 configured to engage the coupling 70 on the proximal end of the

body 28. Distal to the rotational region 618 is a recess 620 in which an elastic or resilient member 622 (e.g., a silicon sleeve) can be placed. As shown in FIG. 9E, when the proximal end of the body 28 is inserted into the lumen 616, the rotational region 618 engages the coupling 70 and the elastic or resilient member 622 grips the body 28 to hold the body 28 in place within the tool 600.

**[0111]** As described above, the insertion tool 600 may be used to rotate the body 28 thereby driving the distal anchor 34 to the desired depth within the pedicle of the vertebrae. The surgeon can stop rotating the body 28 before the distal end of the tool 600 contacts the bone. In embodiments, in which a countersink is formed, the tool 600 can be rotated until the distal end sits within the countersink at which point further rotation of the tool 600 will not cause the distal anchor to advance further as further advancement of the body 28 causes it to be released from the tool 600. In this manner, over advancement of the distal anchor 32 into the vertebrae can be prevented or limited.

**[0112]** It should be appreciated that not all of the steps described above are critical to procedure. Accordingly, some of the described steps may be omitted or performed in an order different from that disclosed. Further, additional steps may be contemplated by those skilled in the art in view of the disclosure herein, without departing from the scope of the present invention.

**[0113]** With reference to FIGS. 1A and 1B, the proximal anchors 50 of the devices 12 extend above the pars such that they abut against the inferior facet of the superior adjacent vertebrae. In this manner, the proximal anchor 50 forms a wedge between the vertebra limiting compression and/or extension of the spine as the facet of the superior adjacent vertebrae abuts against the proximal anchor 50. In this manner, extension is limited while other motion is not. For example, flexion, lateral movement and/or torsion between the superior and inferior vertebra is not limited or constrained. In this manner, the natural motion of the spine can be preserved, especially for those patients with mild or moderate disc conditions. Preferably, the devices are implantable through a minimally invasive procedure and, more preferably, through the use of small percutaneous openings as described above. In this manner, the high cost, lengthy in-patient hospital stays and the pain associated with open procedures can be avoided and/or reduced. In one embodiment, the devices 12 may be removed and/or proximal anchors 50 may be removed in a subsequent procedure if the patient's condition improves. Once implanted, it should be appreciated that, depending upon the clinical situation, the proximal anchor

50 may be positioned such that it contacts surfaces of the adjacent vertebrae all of the time, most of the time or only when movement between the adjacent vertebrae exceeds a limit.

**[0114]** In some instances, the practitioner may decide to use a more aggressive spinal fixation or fusion procedure after an initial period of using the stabilization device 12. In one particular embodiment, the bone stabilization device 12 or a portion thereof may be used as part of the spinal fixation or fusion procedure. In one such application, the proximal anchor 50 can be removed from the body 28. The body 28 can remain in the spine and used to support a portion of a spinal fixation device. For example, the body 28 may be used to support a fixation rod that is coupled to a device implanted in a superior or inferior vertebrae. Examples of such fusion systems can be found in U.S. Patent Application No 10/623,193, filed July 18, 2003, the entirety of which is hereby incorporated by reference herein.

**[0115]** As mentioned above, in certain embodiments described above, it may be advantageous to allow the proximal anchor to rotate with respect to the body 28 thereby preventing the proximal anchor 50 from causing the distal anchor 34 from backing out of the pedicle. In another embodiment, engagement features (as described below) may be added to the proximal anchor 50 to prevent rotation of the proximal anchor 50.

**[0116]** FIG. 1C illustrates a modified embodiment in which the first and second fixation devices 12a, 12b are coupled together by a member 5 that extends generally around or above the spinous process of the superior vertebra 10b. In this manner, the member 5 can be used to limit flexion of the spinal column. The member may comprise an of a variety of suitable structural members. In one embodiment, the member comprises a suture or wire that is tied to the proximal end of the bodies 28 or the proximal anchor. In certain embodiments, various hooks or eyelets can be provided on the body or proximal anchor to facilitate coupling the member to the devices 12a, 12b.

**[0117]** The fixation devices 12 described herein may be made from conventional non-absorbable, biocompatible materials including stainless steel, titanium, alloys thereof, polymers, composites and the like and equivalents thereof. In one embodiment, the distal anchor comprises a metal helix, while the body and the proximal anchor comprise a bioabsorbable material. Alternatively, the distal anchor comprises a

bioabsorbable material, and the body and proximal anchor comprise either a bioabsorbable material or a non-absorbable material.

**[0118]** In one embodiment, the proximal anchor 50 is formed, at least in part, from an elastic and/or resilient material. In this manner, the shock and forces that are generated as the proximal anchor abuts or wedges against the inferior articular process of the superior adjacent vertebrae can be reduced or dissipated. In one such embodiment, the proximal anchor 50 is formed in part by a polycarbonate urethane or a hydrogel. In such embodiments, the elastic material may be positioned on the outer surfaces of the proximal anchor or the portions of the outer surfaces that abut against the surfaces of the inferior articular process of the superior adjacent vertebrae. In one embodiment, such an anchor has an elastic modulus that is lower than metal (e.g, titanium). In another embodiment, the elastic modulus is substantially close to that of bone. In yet another embodiment, the elastic modulus is less than bone. In this manner, the stress risers generated during cyclic loading can be reduced reducing the tendency of the inferior articular process and the inferior vertebrae to crack during cyclic loading.

**[0119]** For example, FIGS. 10A and 10B illustrates an embodiment of device 12' with a proximal anchor 50' that comprises an outer housing or shell 202. The shell 202 may be formed of a resilient material such as, for example, a biocompatible polymer. The proximal anchor 50' also comprises an inner member 204 that comprises a tubular housing 206 and a proximal flange 208. The inner member 202 is preferably formed of a harder more rugged material as compared to the shell 202, such as, for example, titanium or another metallic material. The shell 202 is fitted or formed over the tubular housing 206. When deployed, the shell 202 is held in place between the flange 208 and the surface of the vertebrae in which the body 202 is placed. In modified embodiments, the shell 202 may be coupled to the inner member 204 in a variety of other manners, such as, adhesives, fasteners, interlocking surfaces structures and the like. In the illustrated embodiment, the inner member 204 includes a locking ring 51 positioned within a recess 55 as described above. Of course, in modified embodiments, other retention structures 54 and complementary retention structures 58 may be used between the body 28 and the proximal anchor 50' to permit distal axial travel of the proximal anchor 50' with respect to the body 28, but resist proximal travel of the proximal anchor 50' with respect to the body 28.

[0120] In the illustrated embodiment of FIGS. 10A and 10B, the distal anchor 34 is provided with atraumatic or blunt tip 7. In addition, the flange 72 of the distal anchor 34 includes a square or blunt edges. These features reduce the tendency of the distal anchor to cut into the bone during the window-wiper effect that is caused by cyclic loading of the device as described above.

[0121] In another embodiment, the proximal anchor 50 is provided with a mechanically resilient structure. Thus, as with the previous embodiment, the shock and forces that are generated as the proximal anchor abuts or wedges against the inferior articular process of the superior adjacent vertebrae can be reduced or dissipated. In one such embodiment, the proximal anchor 50 is provided with mechanical springs, lever arms and/or the like. In such embodiments, as the mechanically resilient structure is compressed or extended the shock and forces are reduced or dissipated. .

[0122] For example, FIGS. 11A-13B. illustrate embodiments of a proximal anchor 400, which comprises a tubular housing 402, which includes a recess 403 for receiving a locking ring 51 as described above. The distal end 404 of the housing 402 forms a generally rounded, semi-spherical face that can be inserted into a corresponding counter sink 300 (see FIG. 8) as describe above. Extending from the housings 402 are a plurality of lever arms or deflectable flanges 410. Each arm 410 generally comprises a generally radially extending portion 412 and a generally circumferential extending portion 414. In the illustrated embodiments, two (FIGS. 13A-B), three (FIGS. 12A-B) and five arms (FIGS. 11A-B) are shown. However, the anchor 400 can include different numbers of arms (e.g., one, four or greater than five arms). As the superior adjacent vertebrae 10b moves against the proximal anchor 400 the radially extending portion 414 deflects relative to the tubular housing 402 to absorb or disperse the forces generated by the contact.

[0123] As mentioned above, in the illustrated embodiment, the tubular member 402 includes a locking ring 51 positioned within a recess 403 as described above. Of course, in modified embodiments, other retention structures and complementary retention structures may be used between the body 28 and the proximal anchor 400 to permit distal axial travel of the proximal anchor 400 with respect to the body 28, but resist proximal travel of the proximal anchor 400 with respect to the body 28.

[0124] With reference to FIG. 14, in a modified embodiment, the distal end of the proximal anchor 50 may include one or more bone engagement features 100, which in

the illustrated embodiment comprises a one or more spikes 102 positioned on a contacting surface 104 of the proximal anchors. The spikes 102 provide additional gripping support especially when the proximal anchor 50 is positioned against, for example, uneven bone surfaces and/or soft tissue. In addition, the spikes 102 may limit rotation of the proximal anchor 50 with respect to the body 28 thereby preventing the proximal anchor 50 from backing off the body 28. Other structures for the bone engagement feature 100 may also be used, such as, for example, ridges, serrations etc.

**[0125]** FIGS. 15 and 16 illustrate modified shapes of the proximal anchor which can be used alone or in combination with the elastic or resilient material described above. In FIG. 15, the proximal anchor 250 has a saddle shaped curved surface 251 that generally faces the inferior articular process of the superior adjacent vertebrae. In this embodiment, the saddle shaped surface may limit compression and/or extension of the adjacent vertebra and limit side to side motion and/or torsion between the vertebra. FIG. 16 illustrates an embodiment in which the proximal anchor 350 has a rectangular shape with a flat shaped surface 351. In this embodiment, the flat shaped surface may limit compression and/or extension of the adjacent vertebra and limit side to side motion between the vertebra. In the embodiments of FIGS. 15 and 16, it may be advantageous to limit or eliminate any rotation of the proximal anchor 50 with respect to the body 28 and/or the vertebrae. As such, the proximal anchor 50 preferably includes the retention devices 100 described above with reference to FIG. 14.

**[0126]** As mentioned above, in certain embodiments, clinician will also have an array of proximal anchors 50, having, for example, different configurations and/or shapes. The clinician will choose the appropriate body 28 and then assess the position of the body 28 with respect to the superior vertebrae and chose the proximal anchor 50 from the array, which best fits the patient anatomy to achieve the desired clinical result. In such an embodiment, the proximal anchor 50 is advantageously coupled to body 28 after the body 28 is partially or fully inserted into the vertebrae. The clinician may also be provided with an array of devices for forming differently sized or shaped countersinks corresponding to the different proximal anchors.

**[0127]** As described above, in one embodiment, the proximal anchor 50 is configured such that it can be removed after being coupled and advance over the body 28. In this manner, if the clinician determines after advancing the proximal anchor that the proximal anchor 50 is not of the right or most appropriate configuration (e.g., size and/or

shape), the clinician can remove the proximal anchor 50 and advance a different proximal anchor 50 over the body 28. In such an embodiment, the proximal anchor 50 is preferably provided with one or more engagement structures (e.g., slots, hexes, recesses, protrusions, etc.) configured to engage a rotational and/or gripping device (e.g., slots, hexes, recesses, protrusions, etc.). Thus, in some embodiments, the proximal anchor 50 can be pulled and/or rotated such that the anchor 50 is removed from the body 28.

**[0128]** FIGS. 17 and 18 illustrate an embodiment of a tool 500 that can be used to insert a proximal anchor 50 that utilizes a locking ring 51 (as described above) onto a body 28 of the device 12. In the illustrated embodiment, the tool 500 comprises an elongated body 502 having a distal end 504 and a proximal end 506. The proximal end 506 is provided with a handle 508 for manipulating the tool 500. The distal end 504 of the device is generally tubular and is coupled to or otherwise attached to a distal sleeve 510. The distal sleeve defines a chamber 511, which extends from the distal end 504 of the elongated body 502 to the distal end 513 of the sleeve 510. A guidewire lumen 512 extend through the tool 500.

**[0129]** With particular reference to FIG. 18, a pin 516 is partially positioned within the chamber 511. The pin 516 includes an enlarged proximal portion 518, which is positioned in the chamber 511. The pin 516 also includes an reduced diameter portion 520, which extends outside the chamber 511. A guidewire lumen 522 also extend through the pin 516 such that the entire tool 500 can be inserted over a guidewire. A biasing member 524 is positioned between the distal end 504 of the tubular member 502 the proximal end 518 of the pin 516. In this manner, the pin 516 is biased to the position shown in FIG. 18. Advantageously, the distal end 520 of the pin 516 has an outside diameter that is slightly larger than the inner diameter of the locking ring 51 (see e.g., FIG. 10). Accordingly, the distal end 520 of the pin 516 can be inserted into the proximal anchor through its proximal end. In one embodiment, the locking ring 51 grasps the distal end 520 of the pin 516 to couple the proximal anchor 50 to the pin 516. In the loaded position, the proximal end of the proximal anchor 50 preferably contacts the distal end 513 of the distal sleeve 510.

**[0130]** In use, the tool 500 is coupled to the proximal anchor as described above. After the body 28 is inserted into the vertebrae. The tool 500 is used to position the proximal anchor 50 over the proximal end of the body 28. The tool 500 is then advanced forward. As the tool 500 is advanced forward, the proximal anchor 50 is

pushed onto the body 28 as the pin 516 retracts into the chamber 511. In this manner, the pin 516 holds the locking ring 51 in an expanded position until it engages the body 28. Once the pin 516 is fully retracted into the chamber 511, the pin 516 is decoupled from the proximal anchor 50 and the proximal anchor 50 is fully coupled to the body 28.

**[0131]** In another embodiment, a dimension of the proximal anchor is capable of being adjusted. For example, FIG. 19 illustrates an embodiment of a proximal anchor 700 in which the proximal anchor 700 can be radially expanded such that the relationship between the anchor 700 and the adjacent vertebrae can be adjusted by the surgeon. In this embodiment, the anchor 700 comprises an wall 702, which can be formed of an elastic material. The wall is coupled to an inner member 704 that comprises a tubular housing 706 and a proximal flange 708, which can be arranged as described above with reference to FIG. 10B. The wall 702 and the inner member 704 define a cavity 710, which can be filled with an inflation material 712, such as, for example, a gas, liquid, gel, and/or hardenable or semi-hardenable media (e.g., an polymer, epoxy or cement). One or more valves 714 (e.g., a duck bill valve) can be provided along the wall 702. An inflation lumen 716 can extend through the valve such that the cavity 710 can be inflated with the inflation material 712. After inflation, the lumen 716 is removed and the valve 714 seals the cavity 710. One or more dividing walls 718 can be provided with the cavity 710 such that the anchor 50 can be inflated in discrete or semi-discrete sections.

**[0132]** In one embodiment of use, the body 28 and proximal anchor 700 are inserted into position as described herein. The cavity 710 is then inflated to expand the proximal anchor 50 and increases its diameter. In this manner, the surgeon can control the degree to which the proximal anchor 50 limits the motion of the spine. For example, in one embodiment, increasing the diameter of the proximal anchor 50 would increase the distance between the two vertebrae. In some embodiments, the inflation material 712 can also be removed such that the dimensions can be decreased during the same procedure in which the device 12 is inserted into the spine. In still other embodiments, the inflation material 712 can be added or removed in a subsequent, preferably, minimally invasive second procedure such that the degree which the proximal anchor 50 limits the motion of the spine can be adjusted in the second, subsequent procedure. In one embodiment, this is done by inserting a lumen through the valve and adding and/or removing the inflation media 712.

**[0133]** FIGS. 20A-D illustrates another embodiment of a proximal anchor 750 in which one or more dimensions of the anchor 750 can be adjusted. In this embodiment, the dimensions are adjusted using a mechanical mechanism. With reference to the illustrated embodiment, the anchor 750 can include a proximal member 752 and a distal member 754, which can be moveably carried by the body 28 as described below. The proximal member 752 defines a proximal stop 756 and the distal member 754 defines a distal stop 758. An expandable member 760 is positioned between the proximal and distal stops 756, 758. The expandable member 760 is configured to expand radially as the proximal and distal stops 756, 758 are moved towards each other and the expandable member 760 is compressed therebetween. In one embodiment, the expandable member 760 comprises an elastic material that when compressed expands as shown in FIGS. 20A and 20B. In another embodiment, the expandable member 760 comprises a malleable material (e.g., a metal or metal alloy) that is provided with one or more slots. In such an embodiment, the slots allow the member 760 to expand as it is compressed between the proximal and distal stops 756, 758.

**[0134]** With reference to FIG. 20D, the proximal member 752 can be provided with a recess 55 and ring 51 as described above with reference to FIGS. 5 and 6. In this manner, the proximal member 752 can be advanced in the distal direction while proximal movement of the member 752 is resisted. Of course, other complementary retention structures can be used between the member 752 and the body 28 as described to permit distal movement while resisting proximal movement. The distal movement of the distal member 754 can be prevented by a distal stop 762 provided on the body 28. As shown in FIG. 20D, the distal member 754 can be provided with a smooth bore 764 such that it can be advanced over the body 28 towards the distal stop 762.

**[0135]** FIG. 21 illustrates an embodiment of a proximal anchor 770 which is similar to the previous embodiment. In this embodiment, the proximal member 752 includes threads 772 such that the proximal member 752 can be distally advanced or proximal retracted by rotation. FIG. 22 illustrates another embodiment of a proximal anchor 780. In this embodiment, the proximal member 752 is configured as described with reference FIG. 20D. However, the distal member 754 is provided with threads 782 such that the position of the distal member 754 on the body 28 can be adjusted.

**[0136]** The above described devices and techniques limit motion of the spine by providing an abutment or wedge surface on one vertebrae or body structure. The

abutment surface contacts, abuts, and/or wedges against a portion of a second, adjacent vertebrae or body structure so as limit least one degree of motion between the two vertebra or body structure while permitting at least one other degree of motion. While the above described devices and techniques are generally preferred, certain features and aspects can be extended to modified embodiments for limiting motion between vertebra. These modified embodiments will now be described.

**[0137]** In one embodiment, the proximal anchor 50 of the fixation device may be, coupled to, attached or integrally formed with the body 28. In this manner, movement between the proximal anchor 50 and the body 28 is not permitted. Instead, the clinician may chose a fixation device of the proper length and advance the device into the vertebrae until the proximal anchor lies flush with the vertebrae or is otherwise positioned accordingly with respect to the vertebrae. In one particular, embodiment, the proximal anchor that is coupled to, attached or integrally formed with the body 28 is configured to have an outer surface which can rotate, preferably freely, with respect to the body 28. This arrangement advantageously reduces the tendency of the device to rotate and/or move within the inferior vertebrae as the proximal anchor 50 contacts the superior vertebrae.

**[0138]** In another embodiment, the abutment surface may be attached to the vertebrae through the use of an adhesive, fasteners, staples, screws and the like. In still another embodiment, the abutment surface may formed on a distal end of a stabilization device that is inserted through the front side of the vertebrae.

**[0139]** In the embodiments described above, the device 12 is generally inserted into the spine from a posterior position such that a distal end of the device 12 is inserted into the first, inferior vertebrae and a proximal end of the device 12 contacts or wedges against the second, superior vertebrae. However, it is anticipated that certain features and aspects of the embodiments described herein can be applied to a procedure in which the device is inserted from a lateral or anterior site. In such an embodiment, the distal end or side portion of the device may contact or wedge against the second superior vertebrae. Such embodiments provide a contact or wedge surface which is supported by one body structure to limit of the motion of an adjacent body structure.

**[0140]** In the embodiments, described above, it is generally advantageous that the proximal anchor be radiopaque or otherwise configured such that it can be seen with

visual aids used during surgery. In this manner, the surgeon can more accurately position the proximal anchor with respect to the superior and inferior vertebra.

[0141] Preferably, the clinician will have access to an array of fixation devices 12, having, for example, different diameters, axial lengths and, if applicable, angular relationships. These may be packaged one or more per package in sterile or non-sterile envelopes or peelable pouches, or in dispensing cartridges which may each hold a plurality of devices 12. The clinician will assess the dimensions and load requirements, and select a fixation device from the array, which meets the desired specifications.

[0142] The fixation devices may also be made from conventional non-absorbable, biocompatible materials including stainless steel, titanium, alloys thereof, polymers, composites and the like and equivalents thereof. In one embodiment, the distal anchor comprises a metal helix, while the body and the proximal anchor comprise a bioabsorbable material. In another embodiment, the body is made of PEEK™ polymer or similar plastic material. Alternatively, the distal anchor comprises a bioabsorbable material, and the body and proximal anchor comprise either a bioabsorbable material or a non-absorbable material. As a further alternative, each of the distal anchor and the body comprise a non-absorbable material, connected by an absorbable link. This may be accomplished by providing a concentric fit between the distal anchor and the body, with a transverse absorbable pin extending therethrough. This embodiment will enable removal of the body following dissipation of the pin, while leaving the distal anchor within the bone.

[0143] The components of the present invention may be sterilized by any of the well known sterilization techniques, depending on the type of material. Suitable sterilization techniques include, but not limited to heat sterilization, radiation sterilization, such as cobalt 60 irradiation or electron beams, ethylene oxide sterilization, and the like.

[0144] The specific dimensions of any of the bone fixation devices of the present invention can be readily varied depending upon the intended application, as will be apparent to those of skill in the art in view of the disclosure herein. Moreover, although the present invention has been described in terms of certain preferred embodiments, other embodiments of the invention including variations in dimensions, configuration and materials will be apparent to those of skill in the art in view of the disclosure herein. In addition, all features discussed in connection with any one embodiment herein can be readily adapted for use in other embodiments herein. The use

of different terms or reference numerals for similar features in different embodiments does not imply differences other than those which may be expressly set forth. Accordingly, the present invention is intended to be described solely by reference to the appended claims, and not limited to the preferred embodiments disclosed herein.

WHAT IS CLAIMED IS:

1. A method of limiting extension between an inferior and superior body structure of a spine, comprising: inserting a stabilization into a patient; coupling a stabilization device only to the inferior body structure of the spine such that a portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

2. The method of Claim 1, wherein a distal portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

3. The method of Claim 1, wherein a proximal portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

4. The method of Claim 3, wherein the proximal portion comprises a proximal anchor carried by an elongated body of the stabilization device.

5. The method of Claim 4, further comprising advancing the proximal anchor over the elongated body.

6. A method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient, comprising:

providing a complementary interface on the superior adjacent vertebrae;

advancing a distal end of a stabilization device into the inferior vertebrae;

positioning a proximal portion of the stabilization device such that the proximal portion abuts against the complementary interface to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

7. The method of Claim 6, wherein positioning a proximal portion of the stabilization device comprises advancing a proximal anchor over a body, which forms at least in part, the distal end of the stabilization device.

8. The method of Claim 7, wherein the proximal anchor is advanced over the body after the distal end of the stabilization device is advanced into the inferior vertebrae.

9. The method of Claim 6, wherein advancing a distal end of a stabilization device into the inferior vertebrae comprises rotating the stabilization device.

10. A spinal stabilization device, comprising:

an elongate body, having a proximal end and a distal end;

a distal anchor on the distal end of the elongate body;

a proximal anchor carried to the body and having an outer surface that is radially adjustable with respect to the elongated body.

11. The spinal stabilization device of Claim 10, wherein the proximal anchor is moveably carried by the body and the proximal anchor and the elongated body include complementary retention structures which allow distal movement of the proximal anchor on the body but resist proximal movement of the proximal anchor on the body.

12. The spinal stabilization device of Claim 10, wherein the distal anchor comprises a helical flange.

13. A spinal stabilization device, comprising:  
a body, having a proximal end and a distal end;  
a distal anchor on the distal end of the elongate body;  
a retention structure on the body, proximal to the distal anchor; and  
a proximal anchor, carried by the body, and having a diameter, the proximal anchor having means for adjusting the diameter of the proximal anchor.

14. The spinal stabilization device of Claim 13, wherein the proximal anchor is moveably carried by the body and the proximal anchor and the body include complementary retention structures which allow distal movement of the proximal anchor on the body but resist proximal movement of the proximal anchor on the body.

15. The spinal stabilization device of Claim 13, wherein the distal anchor comprises a helical flange.

16. A method of stabilizing a spine, comprising:  
coupling a stabilization device to an inferior vertebral body such that the stabilization device limits at least one degree of movement between the superior and the inferior vertebrae while not limiting another degree of movement between the superior and inferior vertebrae; and  
in a subsequent procedure, using at least a portion of the stabilization device to support a spinal fixation device configured to allow substantially no movement between the superior and inferior vertebrae.

17. The method of Claim 16, coupling a stabilization device to an inferior vertebral body comprises rotating a helical anchor into the inferior vertebral.

18. The method of Claim 16, coupling a stabilization device to an inferior vertebral body such that the stabilization device limits at least one degree of movement between the superior and the inferior vertebrae while not limiting another degree of

movement between the superior and inferior vertebrae comprises advancing a proximal anchor over an elongated body of the stabilization device and positioning the proximal anchor such that it wedges against the superior vertebrae.

19. A kit for spinal stabilization, comprising:

a spinal stabilization device; and

instructions for coupling the stabilization device only to an inferior body structure of the spine such that a portion of the stabilization device limits extension between the superior body structure and the inferior body structure.

20. A kit as in Claim 19, further comprising instructions to advance a proximal anchor over an elongated body of the stabilization device such that the proximal anchor limits extension between the superior body structure and the inferior body structure.

21. A kit for spinal stabilization, comprising:

a spinal stabilization device comprising a distal end and a proximal end;

instructions for inserting the distal end into an inferior vertebral body and positioning the proximal end of the device such that the device limits extension between the inferior vertebrae and a superior vertebrae body by contacting a surface of the superior vertebrae or an intermediate member coupled to the superior vertebrae.

22. A kit as in Claim 21, further comprising instructions to advance a proximal anchor over an elongated body of the stabilization device such that the proximal anchor limits contacts a surface of the superior vertebrae.

23. A method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient, comprising:

advancing a distal end of a stabilization device into a pedicle of the inferior vertebrae;

positioning a proximal portion of the stabilization device such that the proximal portion limits at least one degree of movement between the superior vertebrae and the inferior vertebrae by contacting a surface of the superior vertebrae; and

removing a portion of the superior vertebrae or the inferior vertebrae to disperse forces generated when the proximal portion of the stabilization device limits at least one degree of movement between a superior vertebrae and an inferior vertebrae by contacting a surface of the superior vertebrae.

24. The method of Claim 23, wherein the step of removing a portion the superior vertebrae or the inferior vertebrae comprises forming a counter sink in the inferior vertebrae for the proximal portion of the stabilization device.

25. The method of Claim 23, wherein the step of removing a portion the superior vertebrae or the inferior vertebrae comprises removing a portion of an inferior articular process of the superior vertebrae.

26. The method of Claim 23, wherein the step of removing a portion the superior vertebrae or the inferior vertebrae comprises forming a recess the superior vertebrae.

27. The method of Claim 23, wherein the step of positioning a proximal portion of the stabilization device comprises advancing a proximal anchor distally over an elongated body of the stabilization device.

28. The method of Claim 27, wherein the step of advancing a proximal anchor distally over an elongated body of the stabilization device comprises proximally retracting the elongated body with respect to the proximal anchor.

29. The method of Claim 27, wherein the step of advancing a proximal anchor distally over an elongated body of the stabilization device comprises applying a distal force to the proximal anchor.

30. The method of Claim 27, further comprising removing the proximal anchor from the elongated body and distally advancing a second proximal anchor over the elongated body of the stabilization device.

31. The method of Claim 23, further comprising maintaining the patient in a face down position during the step of advancing a distal end of a stabilization device into the pedicle of the inferior vertebrae.

32. The method of Claim 23, wherein the step of advancing a distal end of a stabilization device into a pedicle of the inferior vertebrae comprises advancing the distal end of the stabilization device through the pars of the inferior vertebrae.

33. The method of Claim 23, wherein the step of advancing a distal end of a stabilization device into a pedicle of the inferior vertebrae comprises rotating the distal end of the stabilization device.

34. The method of Claim 23, wherein advancing a distal end of a stabilization device into a pedicle of the inferior vertebrae further comprises advancing the stabilization device over a guidewire.

35. A method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient, comprising:

forming a first countersink in the inferior vertebrae;

advancing a distal end of a first stabilization device through the first counter sink and into a pedicle of the inferior vertebrae;

positioning a proximal portion of the first stabilization device such that the proximal portion lies at least partially within the first countersink and abuts against a surface of a first inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between a superior vertebrae and an inferior vertebrae;

forming a second countersink in the inferior vertebrae with substantially bilateral symmetry with respect to the first countersink;

advancing a distal end of a second stabilization device through the second counter sink and into a pedicle of the inferior vertebrae such that it is positioned with substantial bilateral symmetry with respect to the first stabilization device; and

positioning a proximal portion of the second stabilization device at least partially within the second countersink such that the proximal portion abuts, with substantial bilateral symmetry with respect to the first stabilization device, against a surface of second inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

36. The method of Claim 35, wherein the first and second stabilization device limit extension between the superior vertebrae and the inferior vertebrae.

37. The method of Claim 35, wherein the first and second stabilization device limit lateral movement between the superior vertebrae and the inferior vertebrae.

38. The method of Claim 35, further comprising modifying the surface of the first inferior articular process of the superior adjacent vertebrae that abuts against the proximal portion of the first fixation device and modifying the surface of the second inferior articular process of the superior adjacent vertebrae that abuts against the proximal portion of the second fixation device.

39. A method of limiting at least one degree of movement between a superior vertebrae and an inferior vertebrae of a patient, comprising:

modifying a surface of a first inferior articular process of the superior adjacent vertebrae;

advancing a distal end of a first stabilization device into a pedicle of the inferior vertebrae;

positioning a proximal portion of the first stabilization device such that the proximal portion abuts against the modified surface of the first inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between a superior vertebrae and an inferior vertebrae;

modifying a surface of a second inferior articular process of the superior adjacent vertebrae;

advancing a distal end of a second stabilization device into a pedicle of the inferior vertebrae such that it is positioned with substantial bilateral symmetry with respect to the first stabilization device; and

positioning a proximal portion of the second stabilization device such that the proximal portion abuts, with substantial bilateral symmetry with respect to the first stabilization device, against the modified surface of second inferior articular process of the superior adjacent vertebrae to limit at least one degree of movement between the superior vertebrae and the inferior vertebrae.

40. A spinal stabilization device, comprising:

an elongate body, having a proximal end and a distal end;

a distal anchor on the distal end of the elongate body;

a retention structure on the body, proximal to the distal anchor; and

a proximal anchor, moveably carried by the body, the proximal anchor having an outer surface, at least a portion of the outer surface being mechanically resilient; and

at least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

41. The spinal stabilization device of Claim 40, wherein the distal anchor comprises a helical flange.

42. The spinal stabilization device of Claim 40, wherein the retention structure on the body and the least one complementary retention structure on the proximal anchor comprise a series of ridges and grooves.

43. The spinal stabilization device of Claim 42, wherein the least one complementary retention structure on the proximal anchor comprises an annular ring positioned within a recess formed between the proximal anchor and the elongate pin.

44. The spinal stabilization device of Claim 43, wherein the mechanically resilient structure comprises a deflectable flange.

45. A spinal stabilization device, comprising:

- an elongate body, having a proximal end and a distal end;
- a distal anchor on the distal end of the elongate body;
- a retention structure on the body, proximal to the distal anchor; and
- a proximal anchor, moveably carried by the body, the proximal anchor having an outer surface, at least a portion of the outer surface having an elastic modulus that is substantially similar to bone; and
- at least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

46. A method of limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient, comprising:

- advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body; and

- positioning a proximal portion of the stabilization device such that the proximal portion limits at least one degree of movement between a superior vertebral body and an inferior vertebral body by contacting a surface of the superior vertebral body.

47. The method of Claim 46, wherein the step of positioning a proximal portion of the stabilization device comprises advancing a proximal anchor distally over an elongated body of the stabilization device.

48. The method of Claim 47, wherein the step of advancing a proximal anchor distally over an elongated body of the stabilization device comprises proximally retracting the elongated body with respect to the proximal anchor.

49. The method of Claim 47, wherein the step of advancing a proximal anchor distally over an elongated body of the stabilization device comprises applying a distal force to the proximal anchor.

50. The method of Claim 46, further comprising maintaining the patient in a face down position during the step of advancing a distal end of a stabilization device into the pedicle of the inferior vertebral body.

51. The method of Claim 50, wherein the step of advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body comprises advancing the distal end of the stabilization device through the pars of the inferior vertebral body.

52. The method of Claim 46, wherein the steps of advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body and positioning a proximal portion of the stabilization device are accomplished through a minimally invasive surgical approach.

53. The method of Claim 46, wherein the step of advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body comprises rotating the distal end of the stabilization device.

54. The method of Claim 46, wherein advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body further comprises advancing the stabilization device over a guidewire.

55. The method of Claim 46, wherein advancing a distal end of a stabilization device into a pedicle of the inferior vertebral body further comprises advancing the stabilization device through an expanded tissue tract.

56. A method of limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient, comprising:

advancing a distal end of a first stabilization device into a pedicle of the inferior vertebral body;

positioning a proximal portion of the first stabilization device such that the proximal portion abuts against a surface of an inferior articular process of the superior adjacent vertebral body to limit at least one degree of movement between a superior vertebral body and an inferior vertebral body;

advancing a distal end of a second stabilization device into a pedicle of the inferior vertebral body such that it is positioned with bilateral symmetry with respect to the first stabilization device; and

positioning a proximal portion of the second stabilization device such that the proximal portion abuts, with bilateral symmetry with respect to the first stabilization device, against a surface of second inferior articular process of the superior adjacent vertebral body to limit at least one degree of movement between the superior vertebral body and the inferior vertebral body.

57. The method of Claim 56, wherein the first and second stabilization device limit flexion between the superior vertebral body and the inferior vertebral body.

58. The method of Claim 56, wherein the first and second stabilization device limit lateral movement between the superior vertebral body and the inferior vertebral body

59. A spinal stabilization device, comprising:  
an elongate body, having a proximal end and a distal end;  
a distal anchor on the distal end of the elongate body;  
a retention structure on the body, proximal to the distal anchor; and  
a proximal anchor, moveably carried by the body, the proximal anchor having an outer surface, at least a portion of the outer surface being elastic; and  
at least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

60. The spinal stabilization device of Claim 59, wherein the distal anchor comprises a helical flange.

61. The spinal stabilization device of Claim 59, wherein the retention structure on the body and the least one complementary retention structure on the proximal anchor comprise a series of ridges and grooves.

62. The spinal stabilization device of Claim 60, wherein the least one complementary retention structure on the proximal anchor comprises an annular ring positioned within a recess formed between the proximal anchor and the elongate pin.

63. The spinal stabilization device of Claim 59, wherein the proximal anchor includes a distally facing surface, the distally facing surface including at least one bone engagement feature.

64. A spinal stabilization device for limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient, comprising:

an elongate body, having a proximal end and a distal end;

a distal anchor on the distal end of the elongate body;  
a retention structure on the body, proximal to the distal anchor; and  
a proximal anchor, moveably carried by the body, and including at least one flat surface configured to abut against a surface of an inferior articular process of the superior adjacent vertebral body when the stabilization device is inserted into the inferior adjacent vertebral body ; and

at least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

65. A spinal stabilization device for limiting at least one degree of movement between a superior vertebral body and an inferior vertebral body of a patient, comprising:

an elongate body, having a proximal end and a distal end;  
a distal anchor on the distal end of the elongate body;  
a retention structure on the body, proximal to the distal anchor; and  
a proximal anchor, moveably carried by the body and including at least one saddle-shaped surface configured to abut against an inferior articular process of the superior adjacent vertebral body when the stabilization device is inserted into the inferior adjacent vertebral body ; and

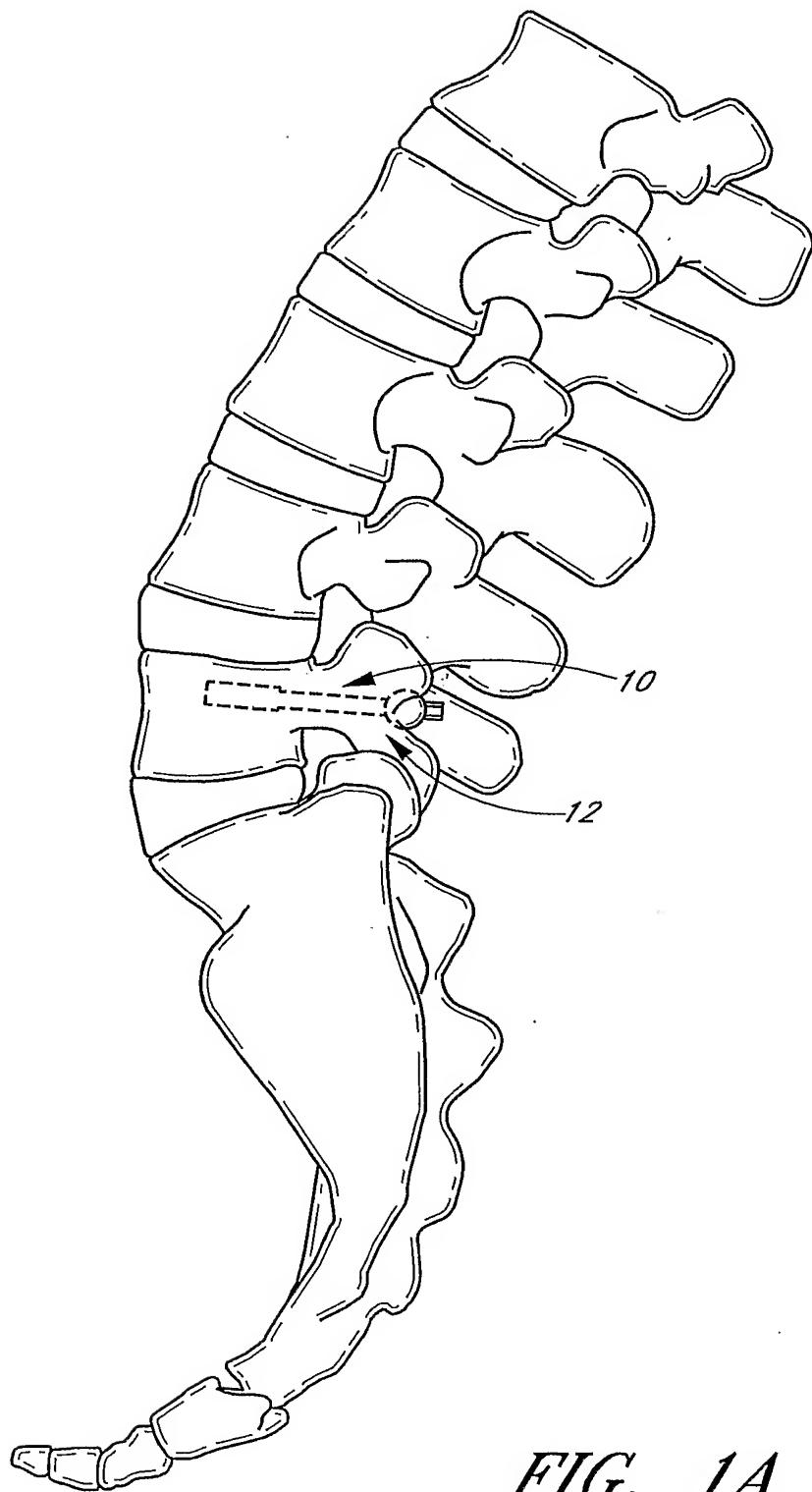
at least one complementary retention structure on the proximal anchor configured for permitting proximal movement of the body with respect to the proximal anchor but resisting distal movement of the body with respect the proximal anchor.

66. A spinal stabilization device, comprising:

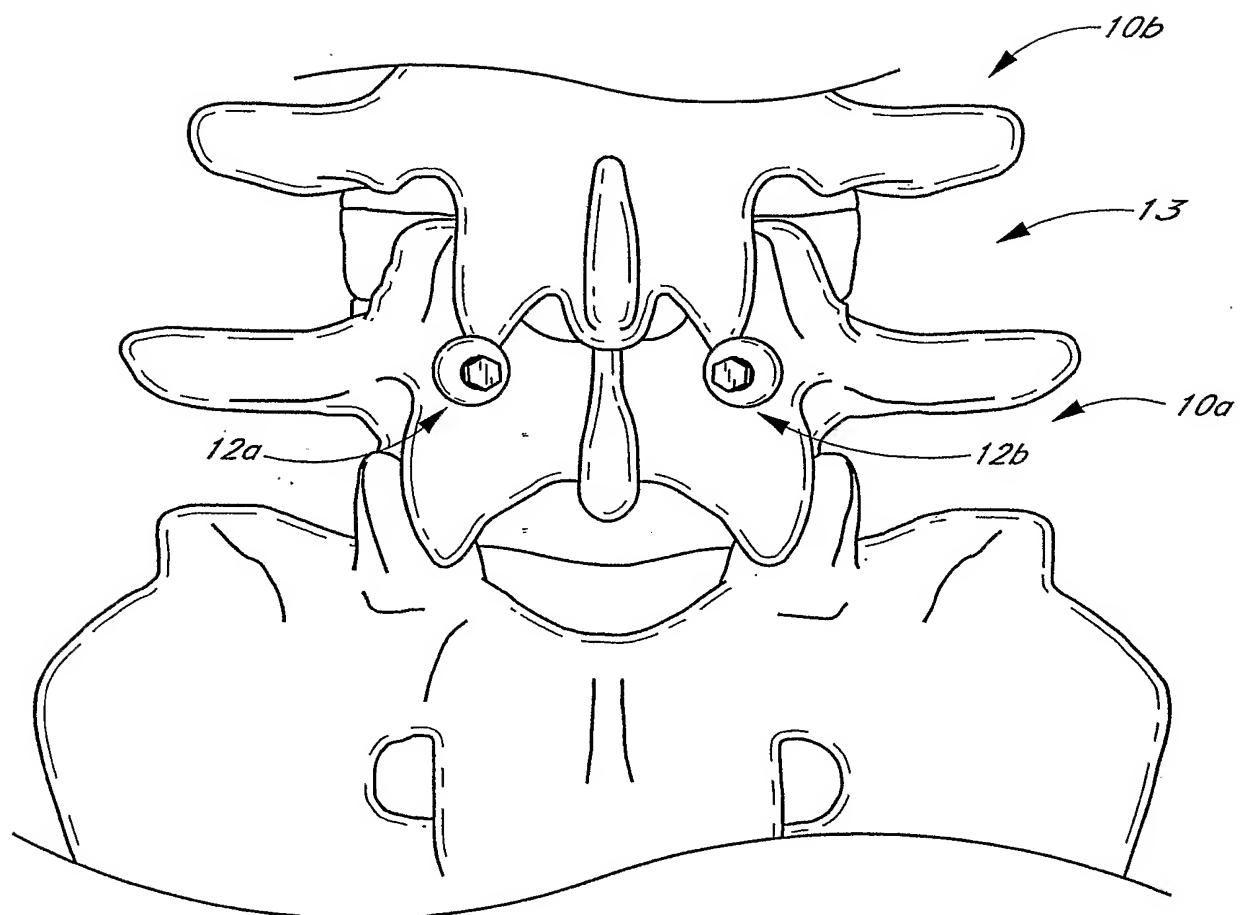
an elongate body, having a proximal end and a distal end; and  
means for wedging the proximal against a superior inferior body structure when the distal anchor is inserted into an inferior body structure such that the stabilization device limits extension between the superior body structure and the inferior body structure.

67. The device of Claim 66, further comprising a distal anchor on the distal end of the elongate body.

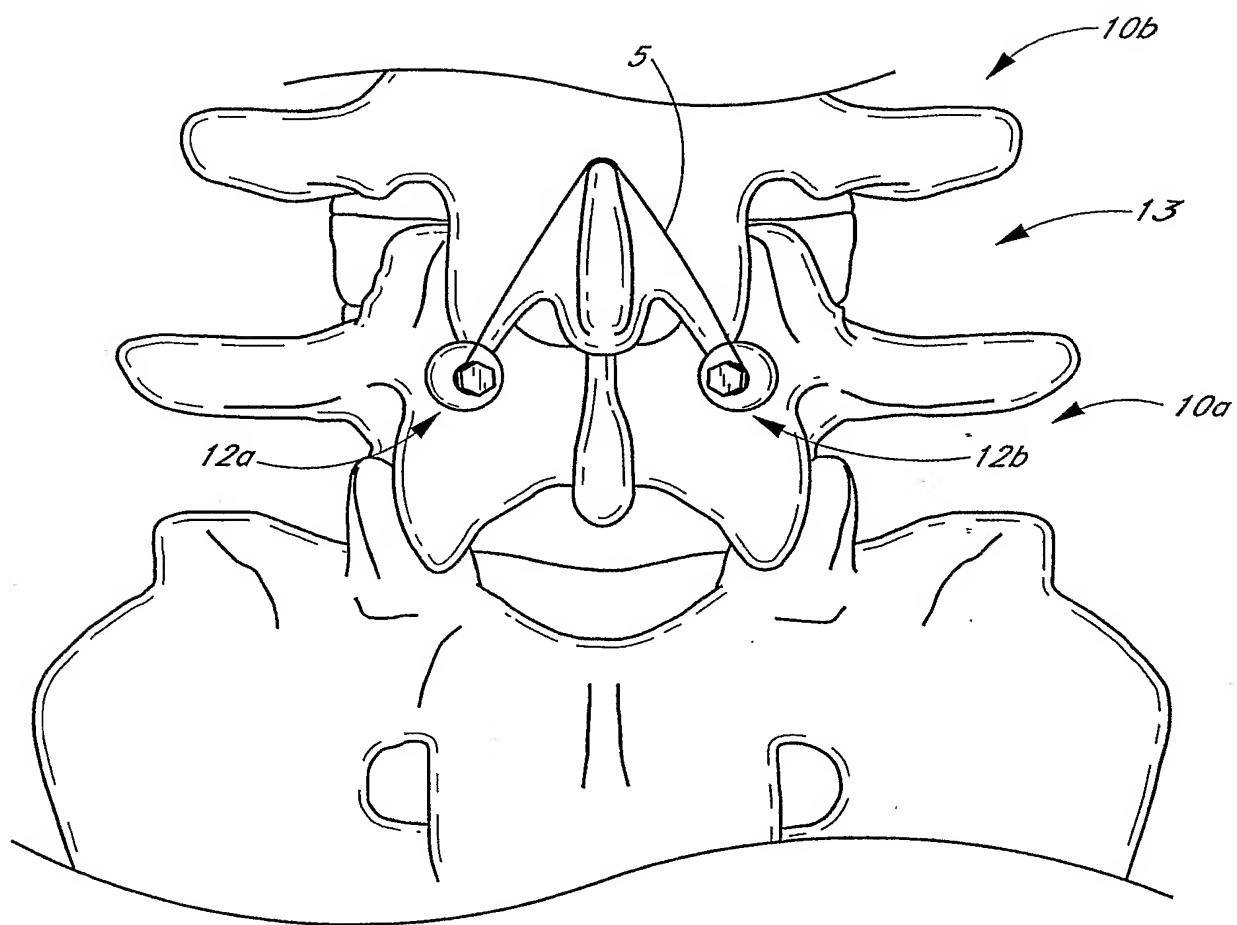
68. The device of Claim 66, further comprising a proximal anchor moveably carried by the elongated body.



*FIG. 1A*



*FIG. 1B*



*FIG. 1C*

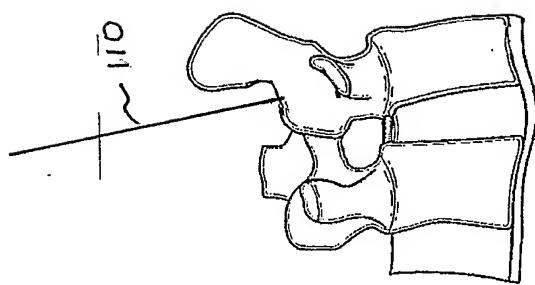


FIG. 1D

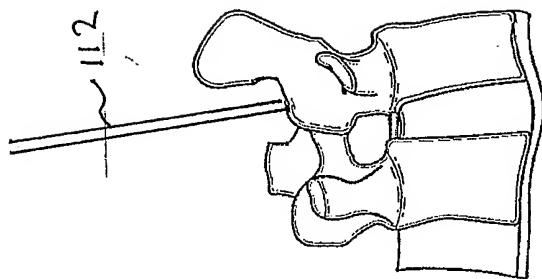


FIG. 1 E

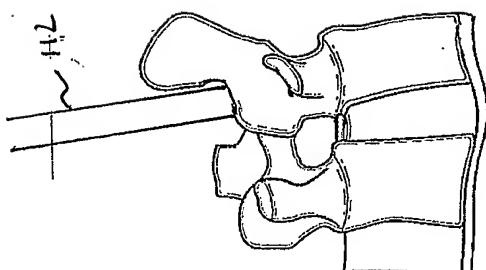
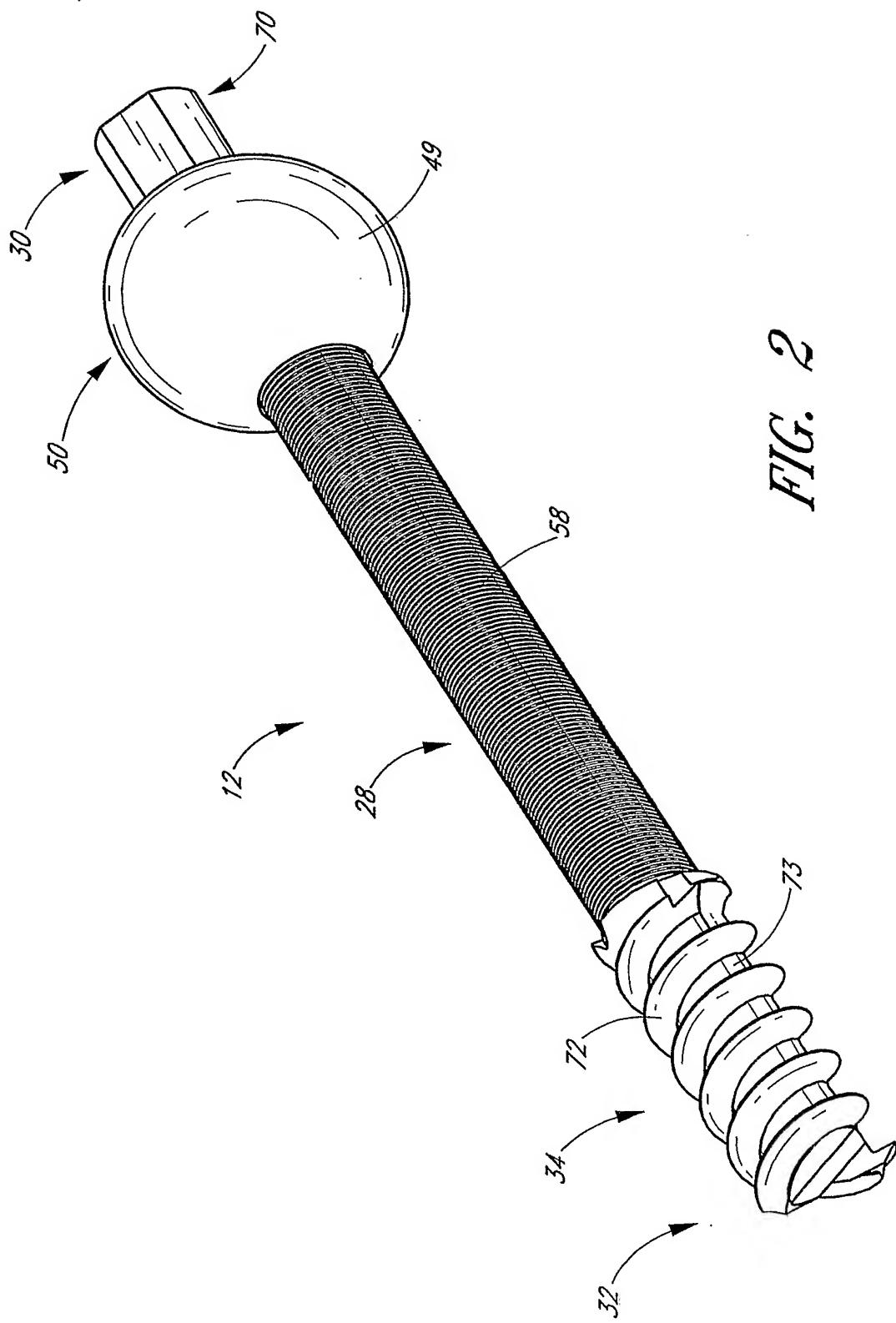


FIG. 1F



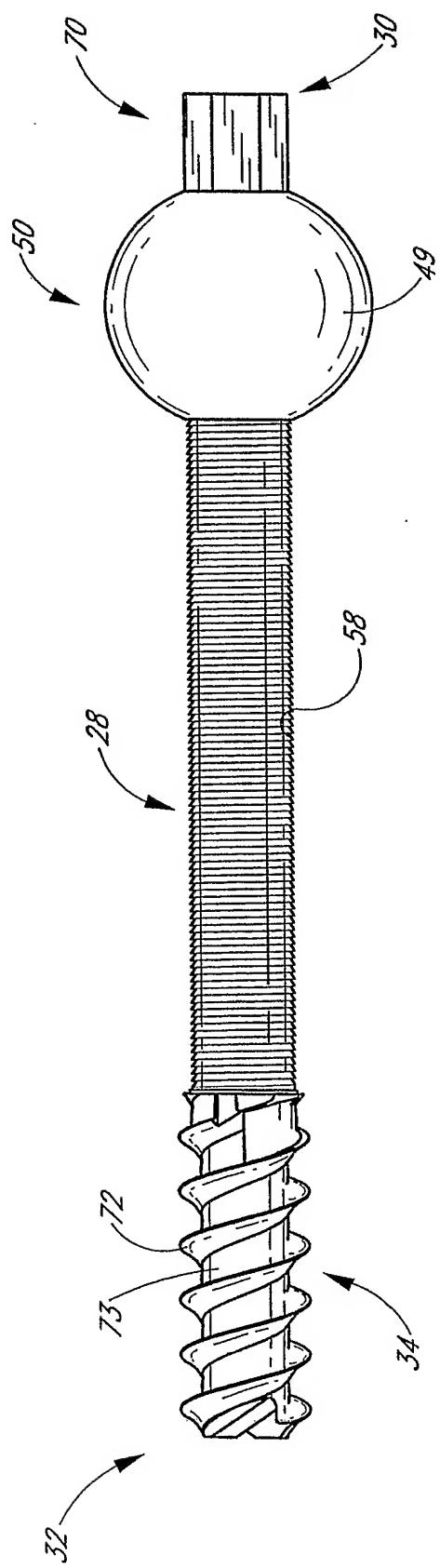


FIG. 3

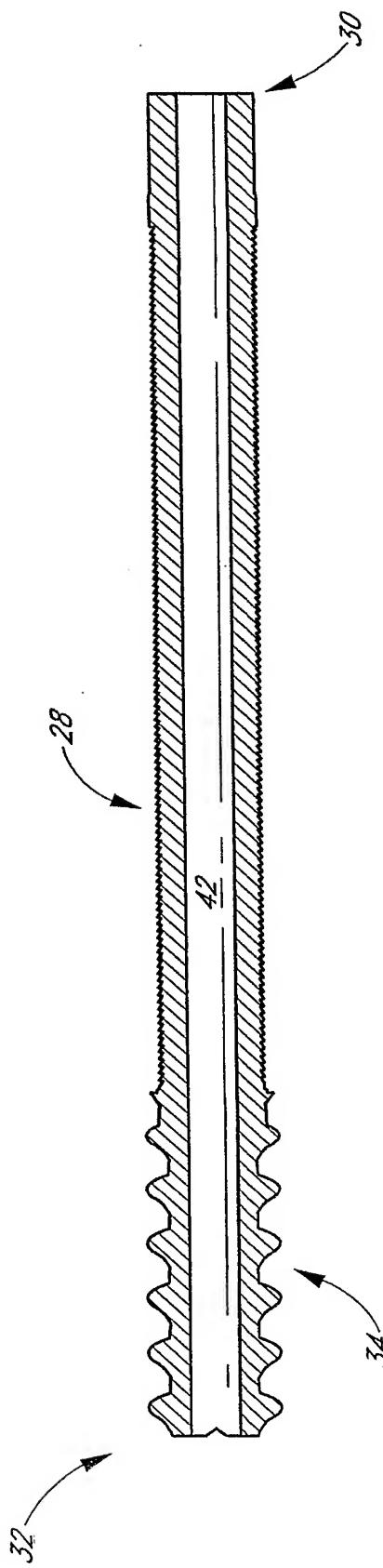


FIG. 3A

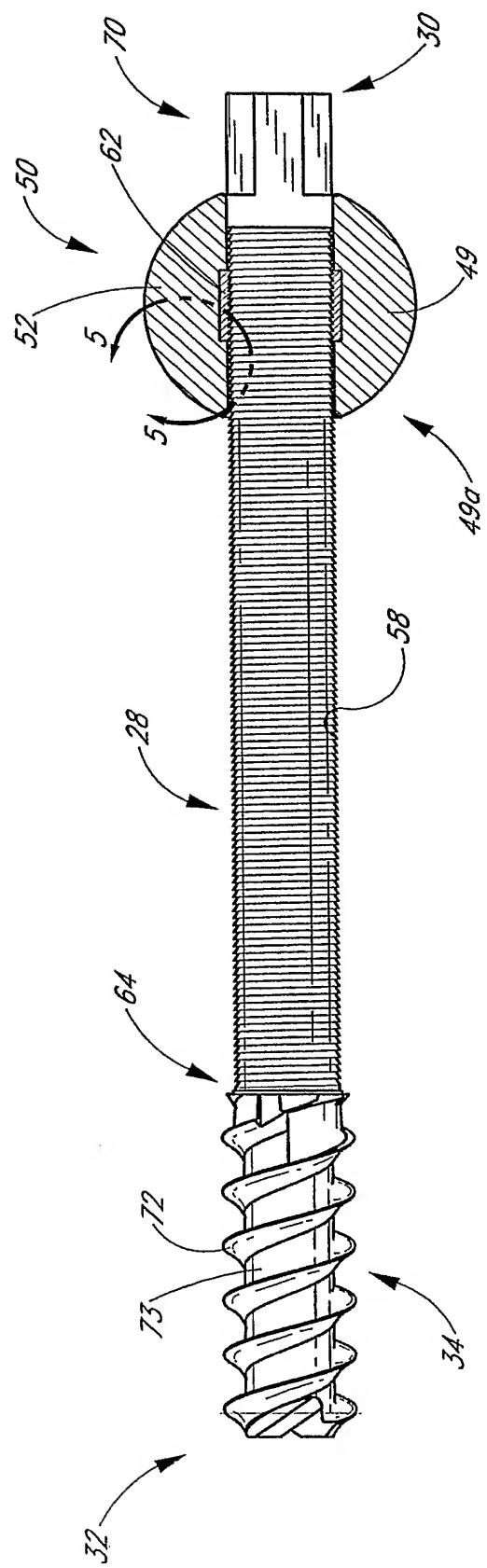


FIG. 4

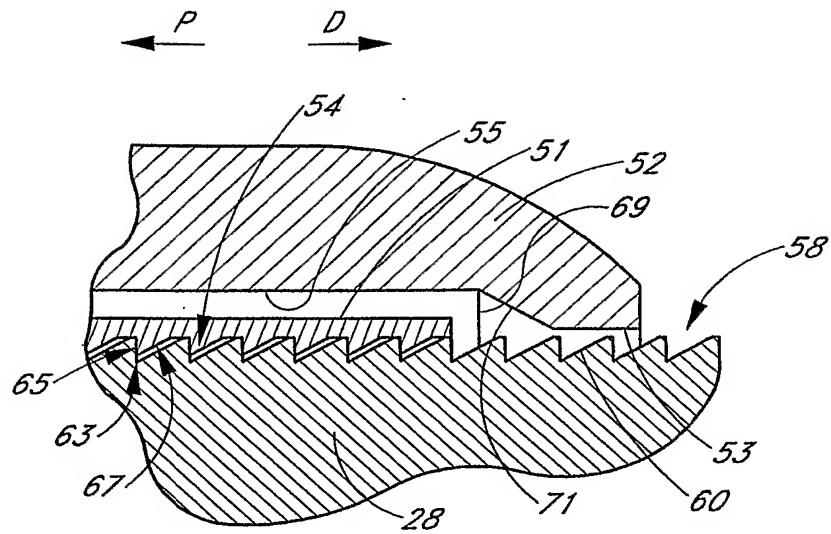


FIG. 5

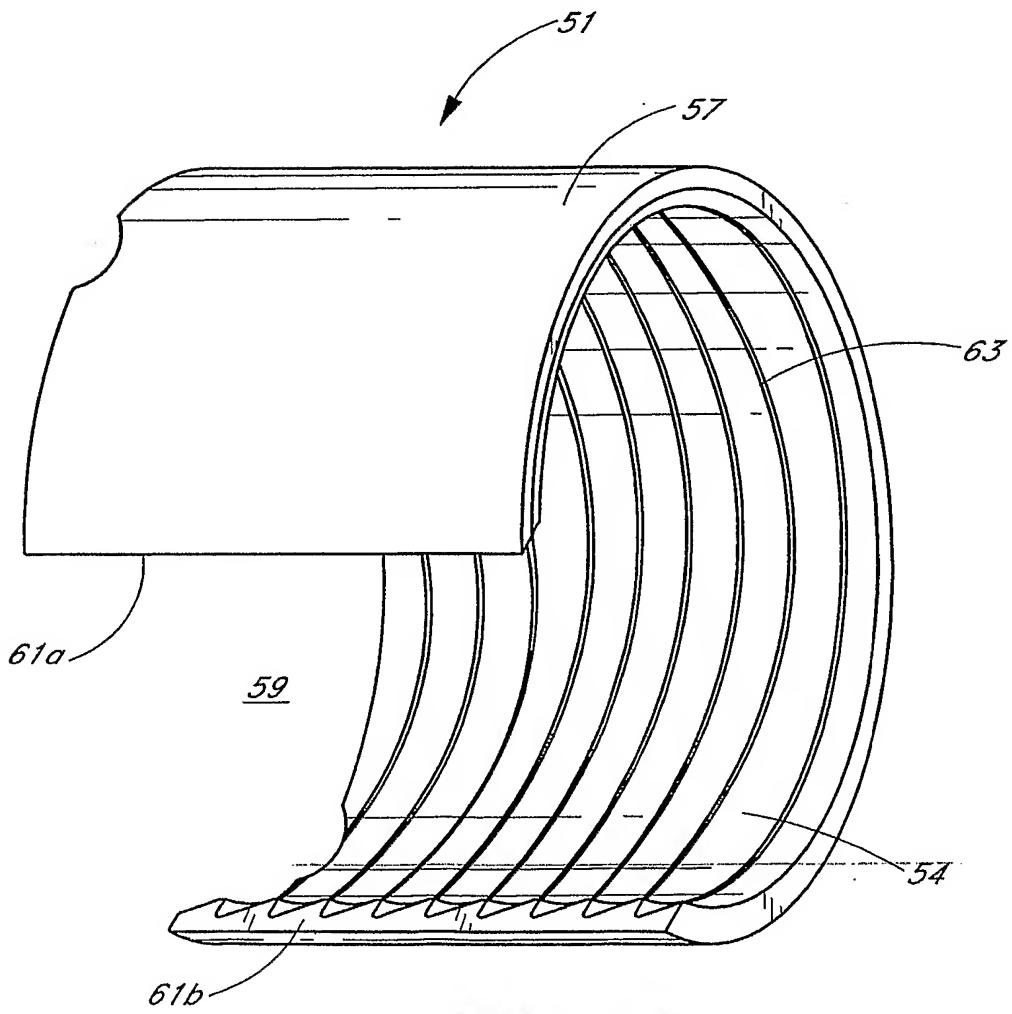


FIG. 6

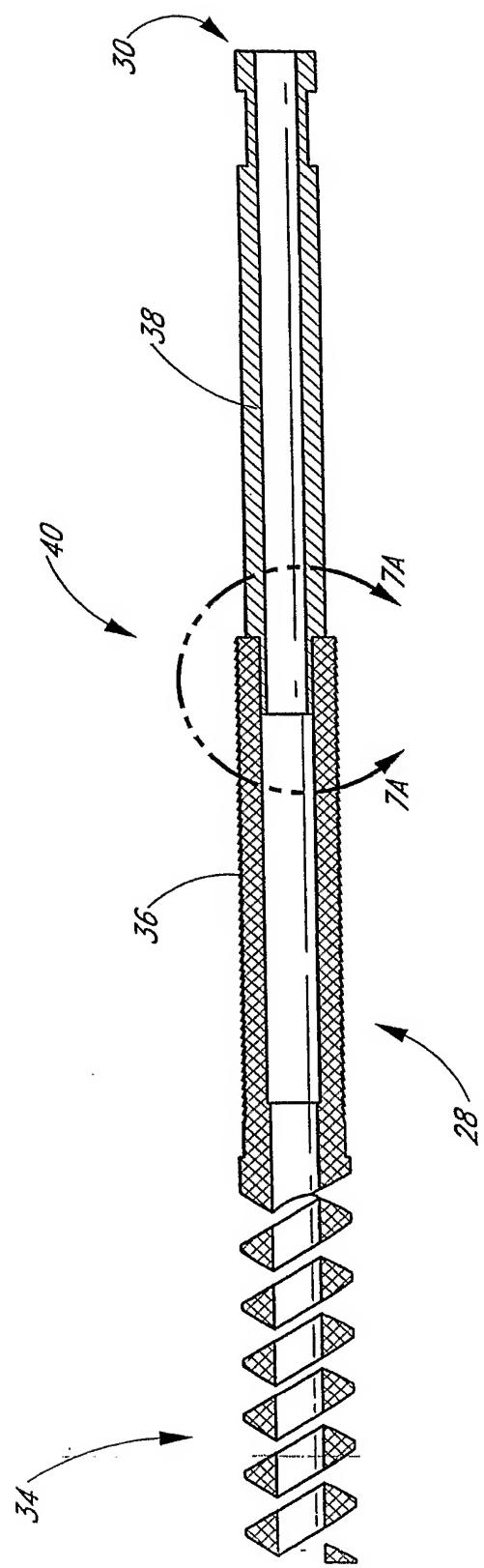
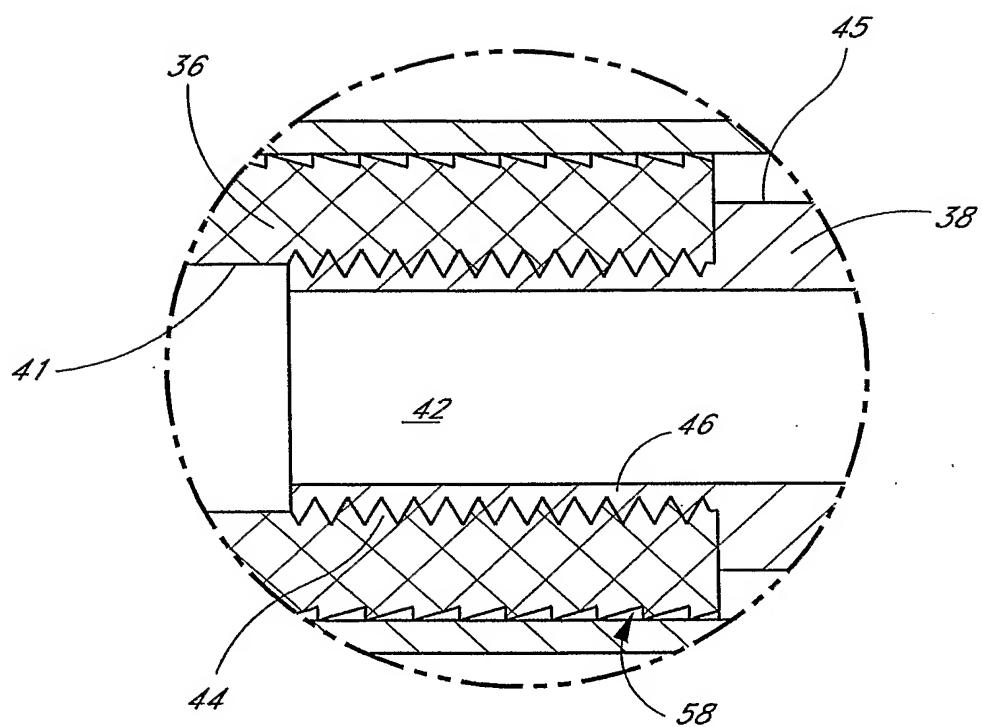
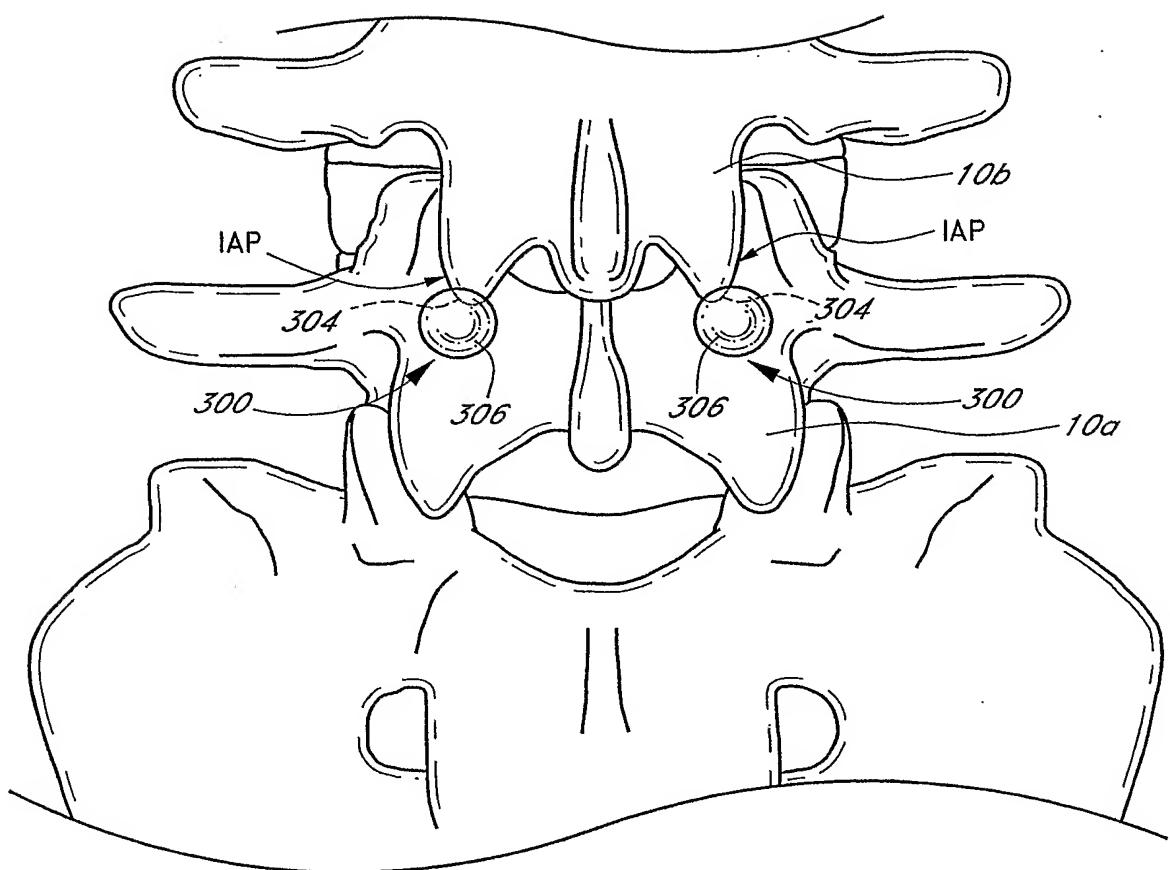


FIG. 7



*FIG. 7A*



*FIG. 8*

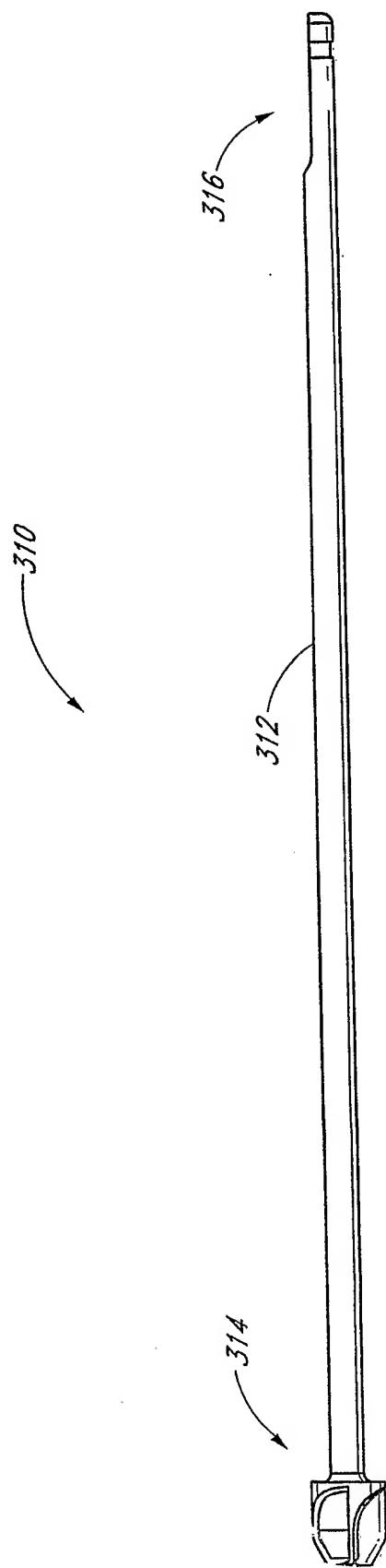


FIG. 9A

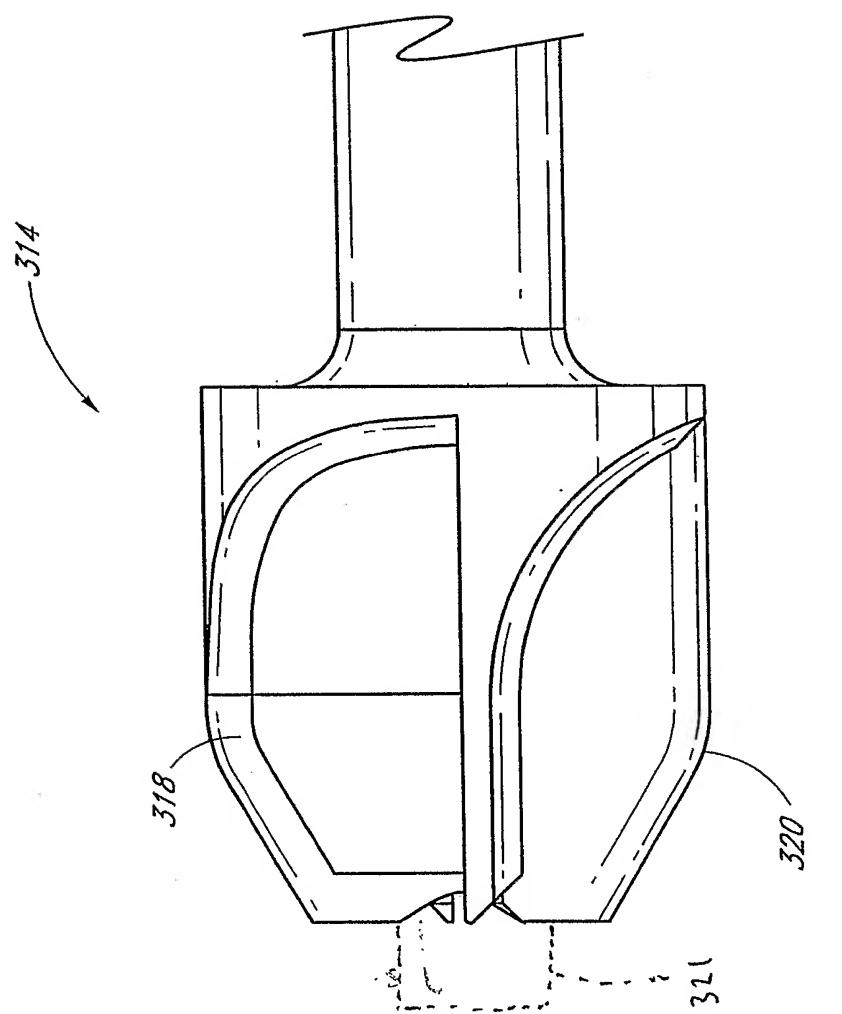


FIG. 9B

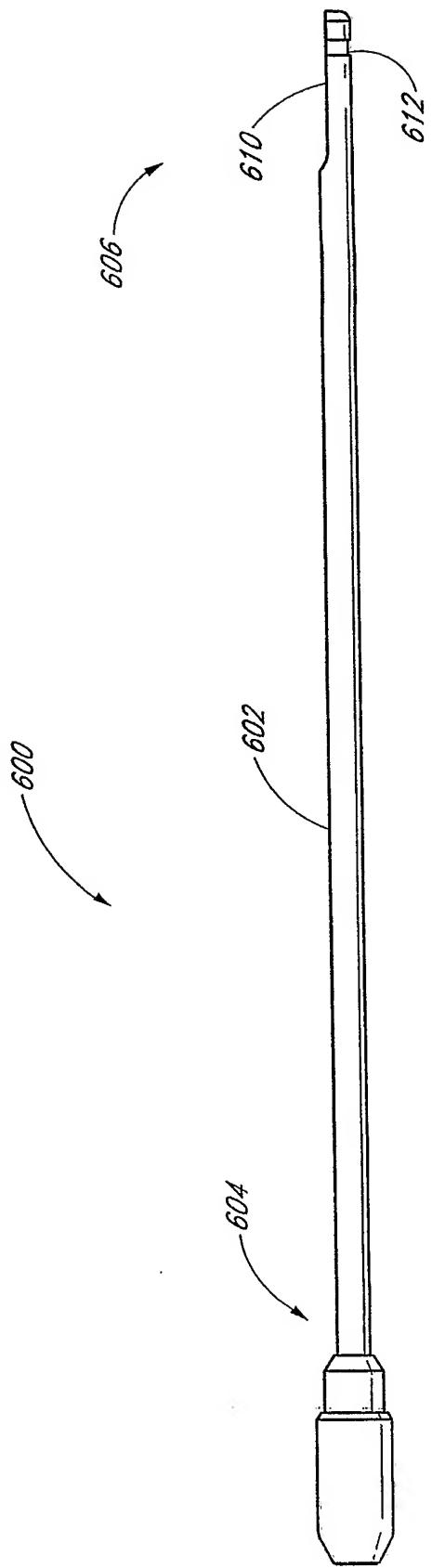


FIG. 9C

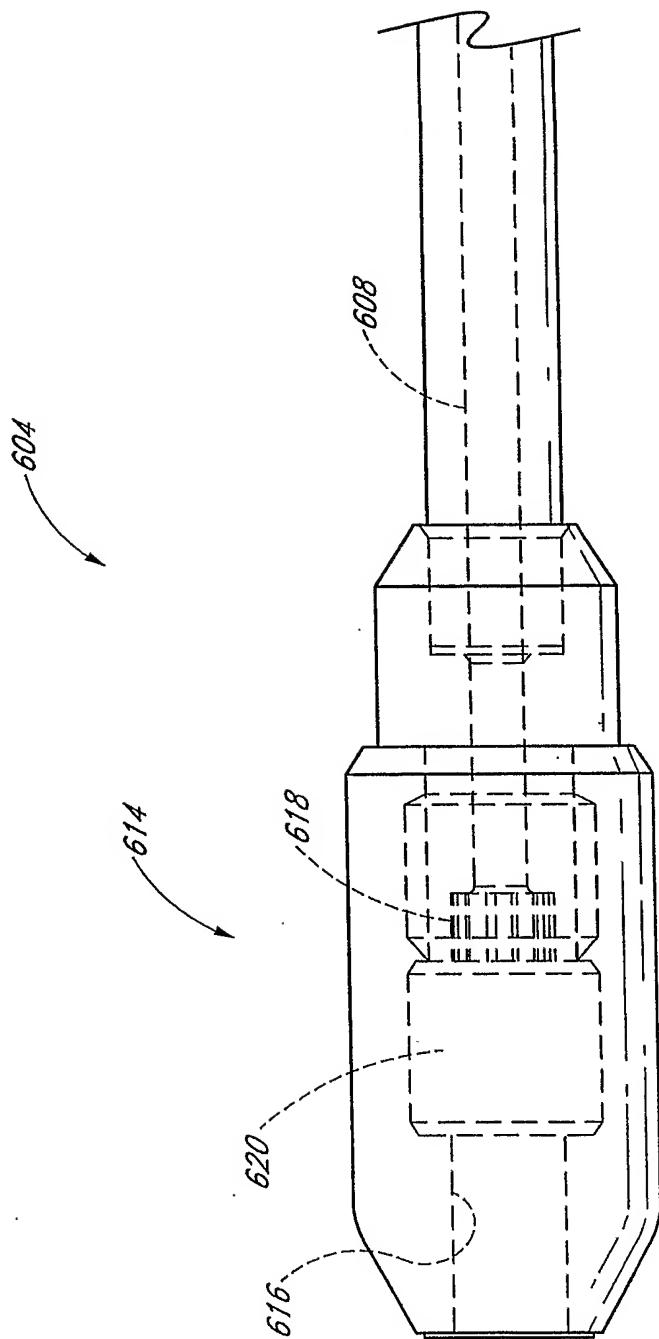


FIG. 9D

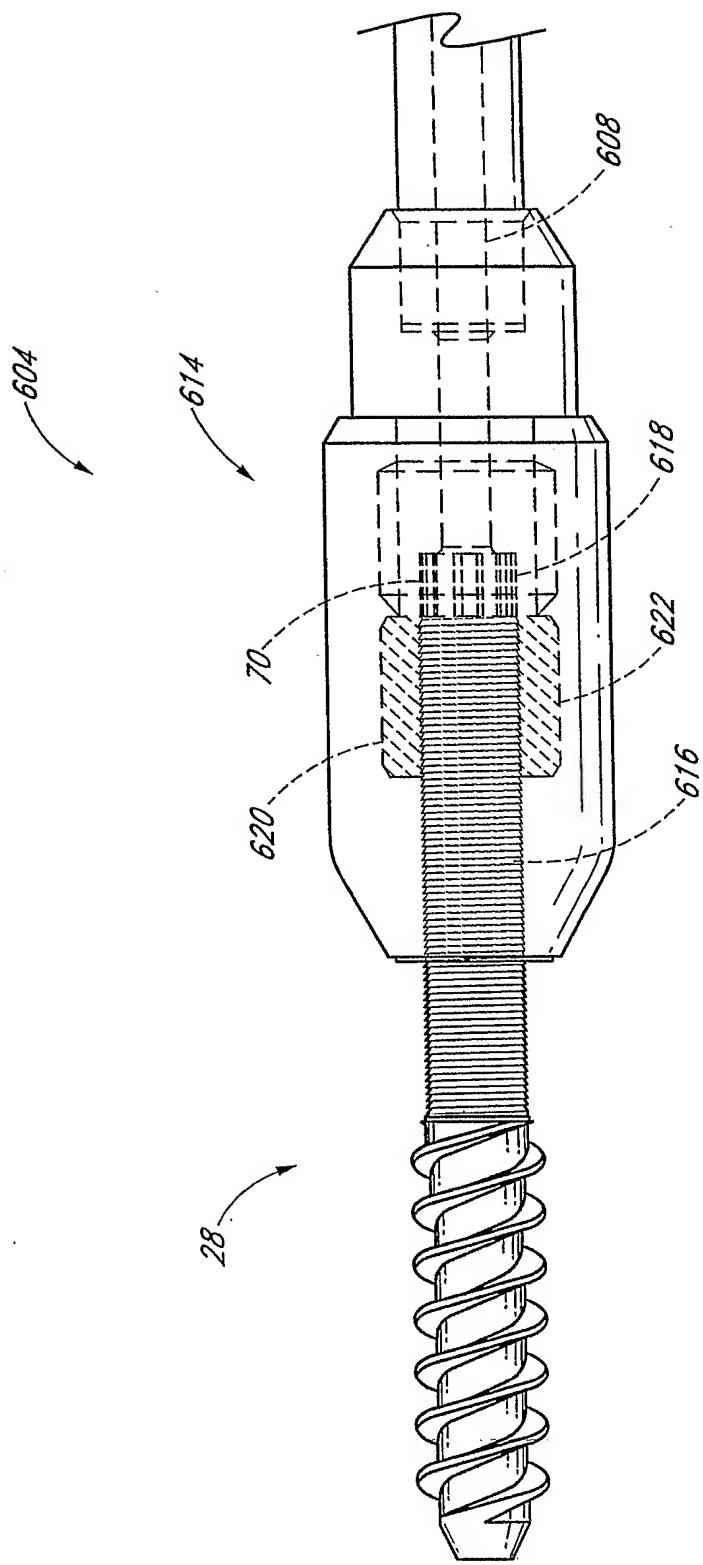


FIG. 9E

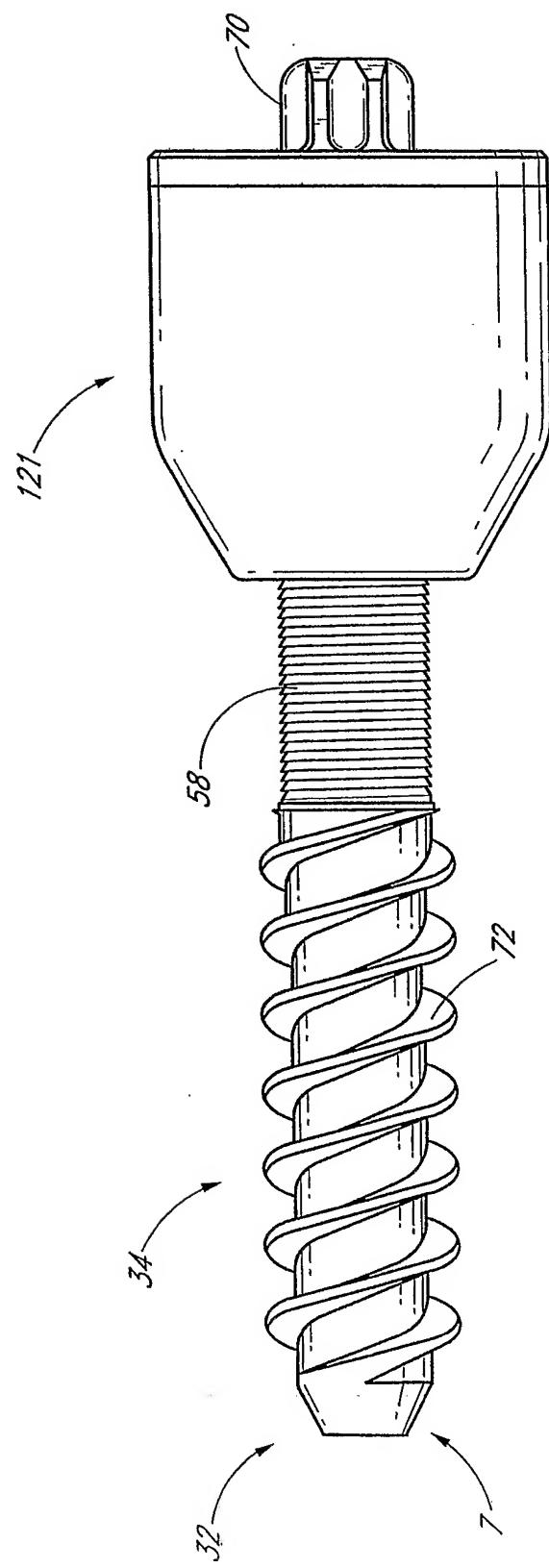


FIG. 10A

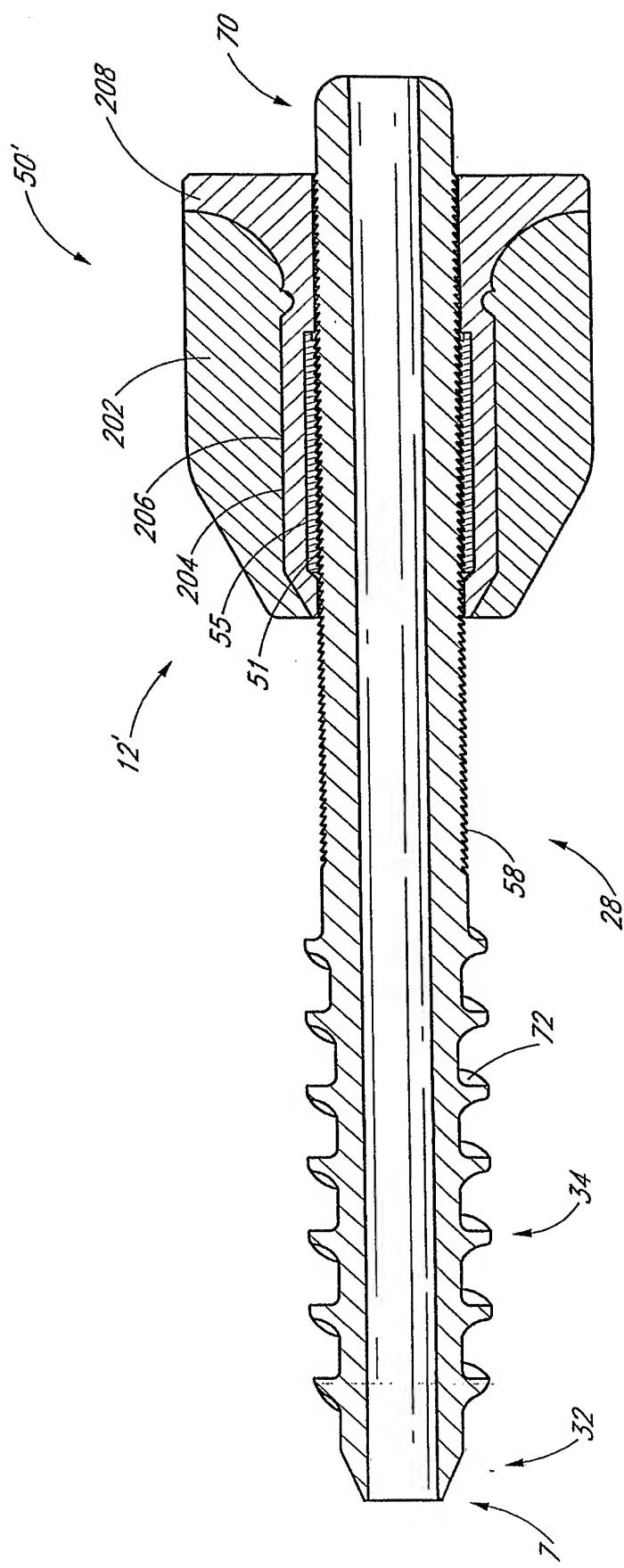


FIG. 10B

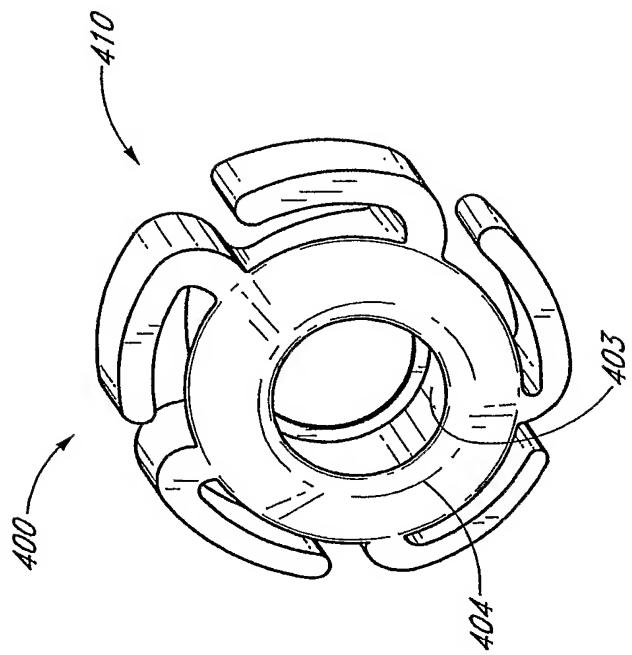


FIG. 11B

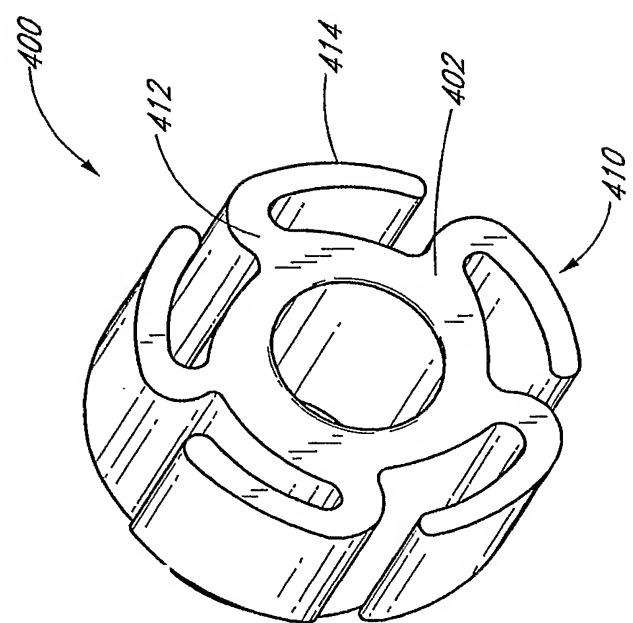


FIG. 11A

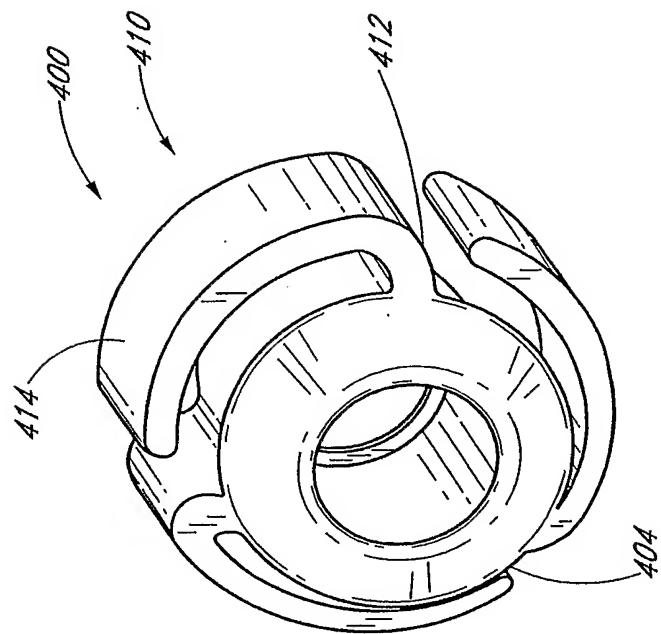


FIG. 12B

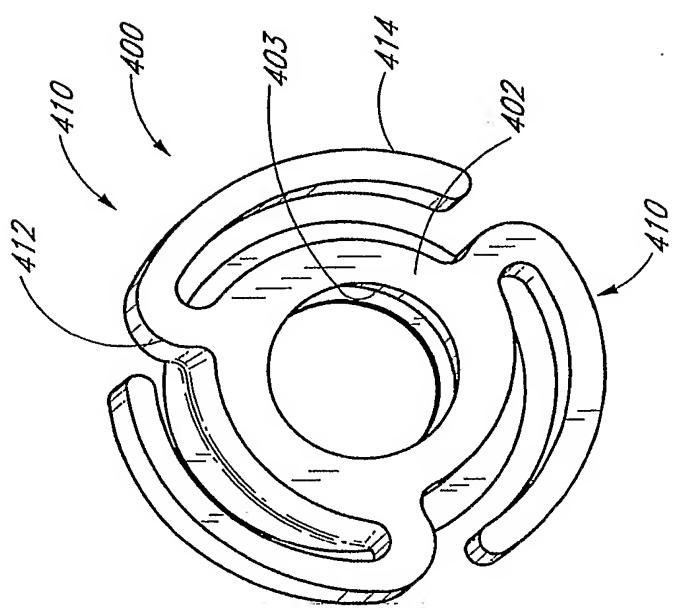
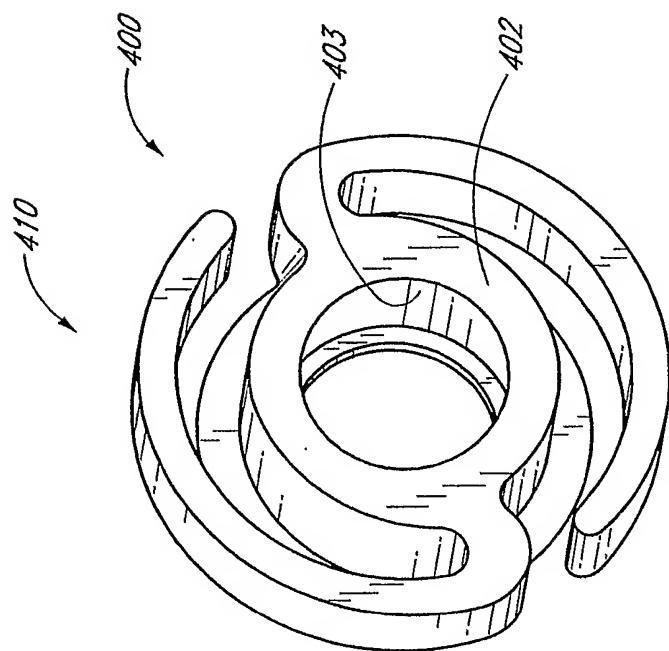
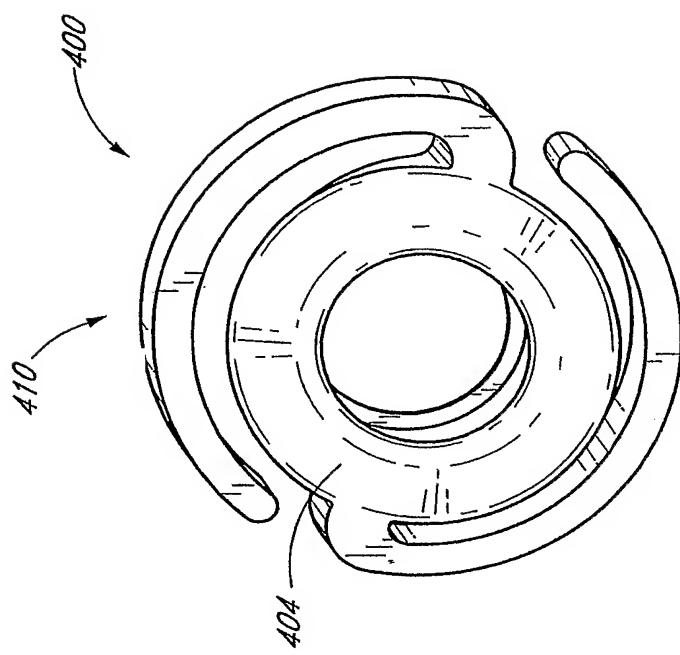


FIG. 12A



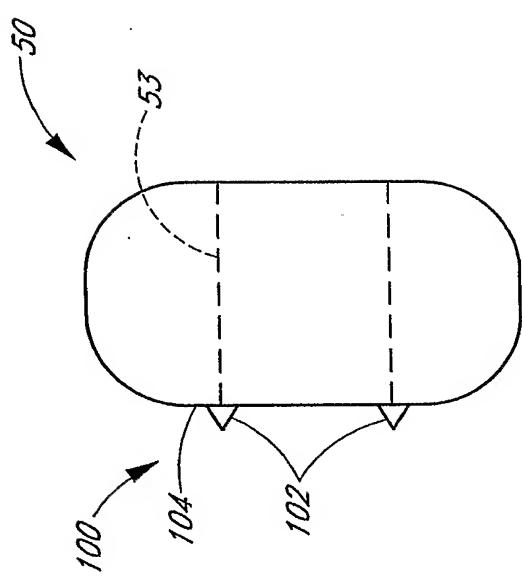


FIG. 14

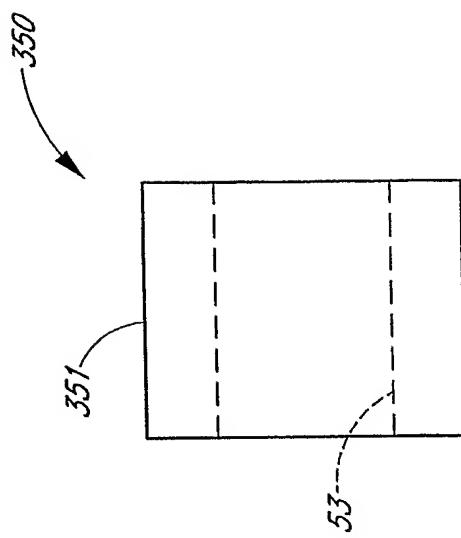


FIG. 16

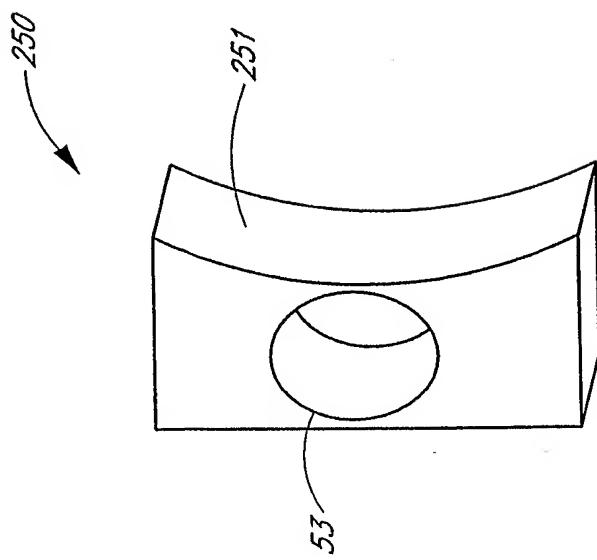
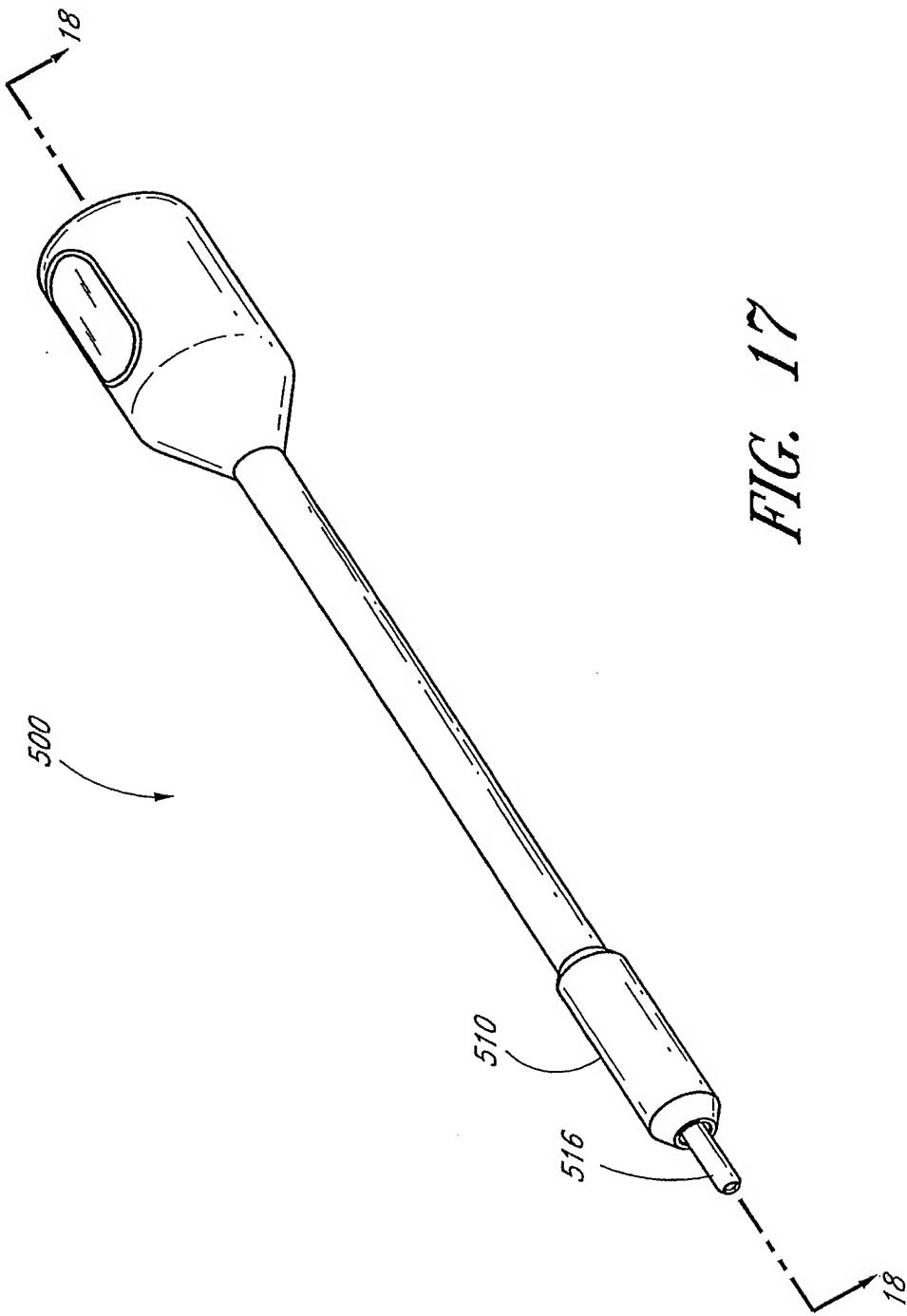


FIG. 15



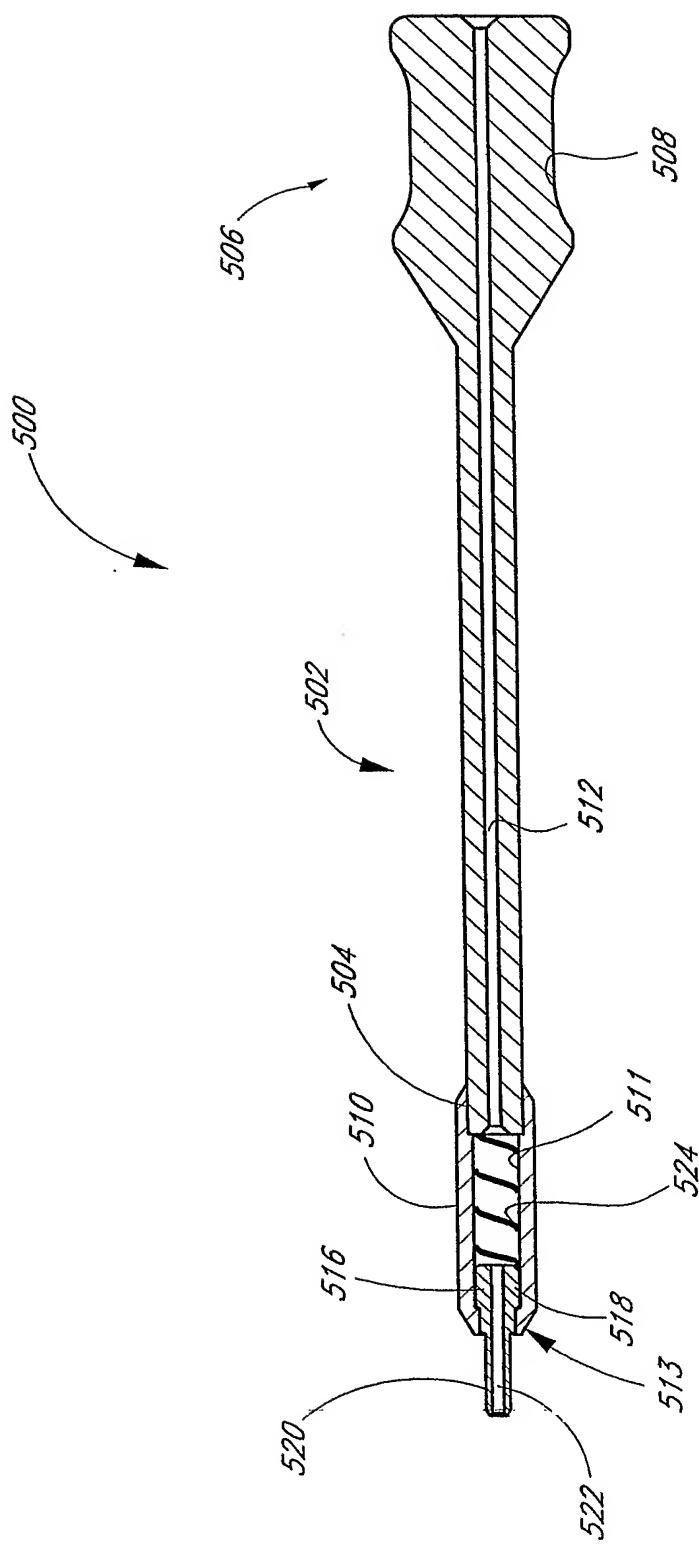


FIG. 18

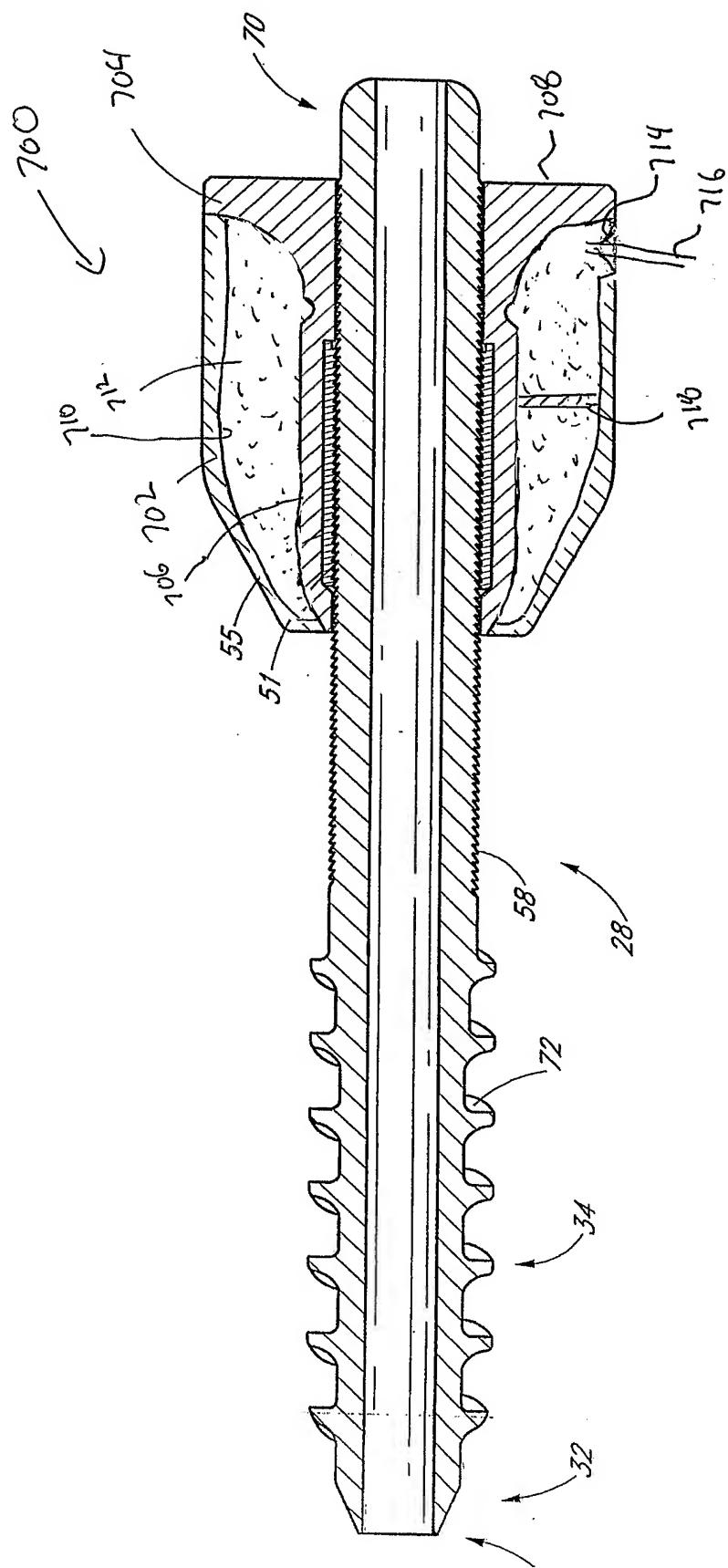


FIG. 19

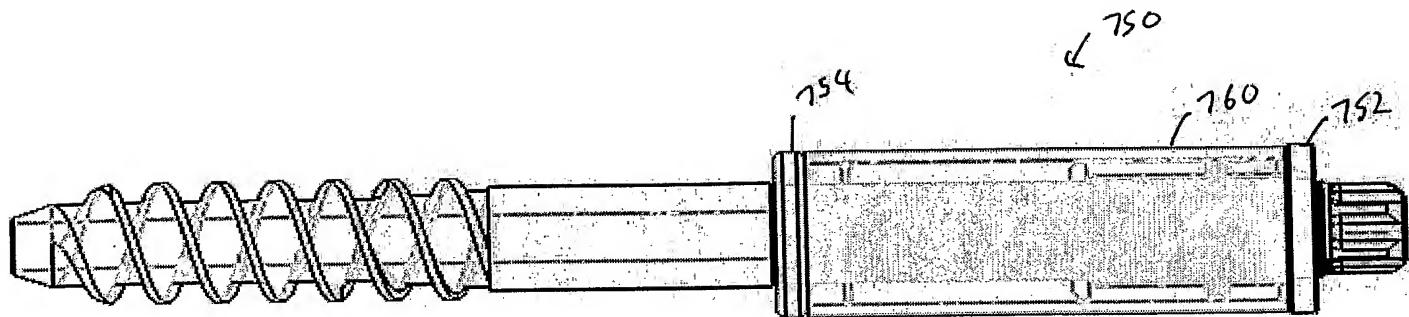


Fig 20A

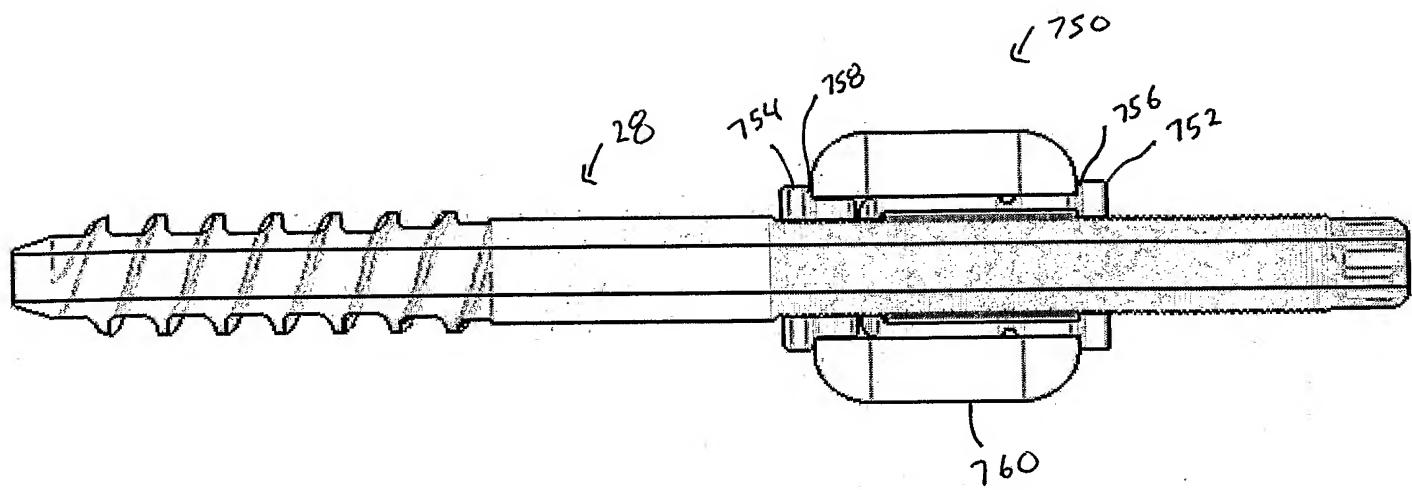


Fig. 20B

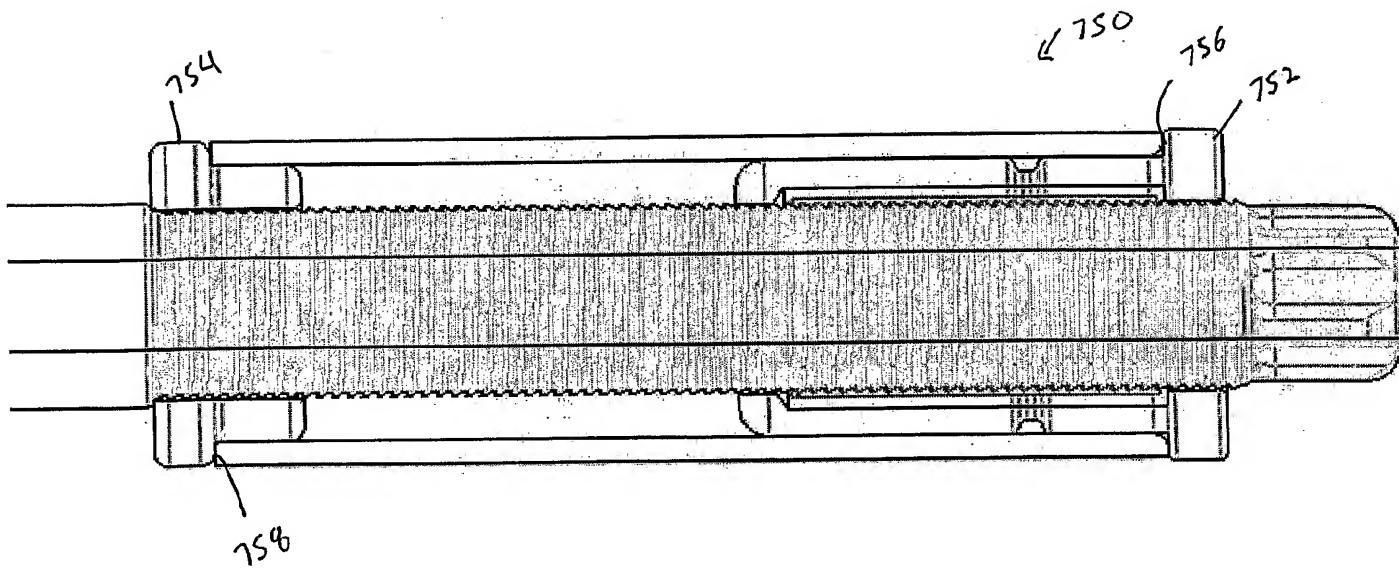


Fig. 20C

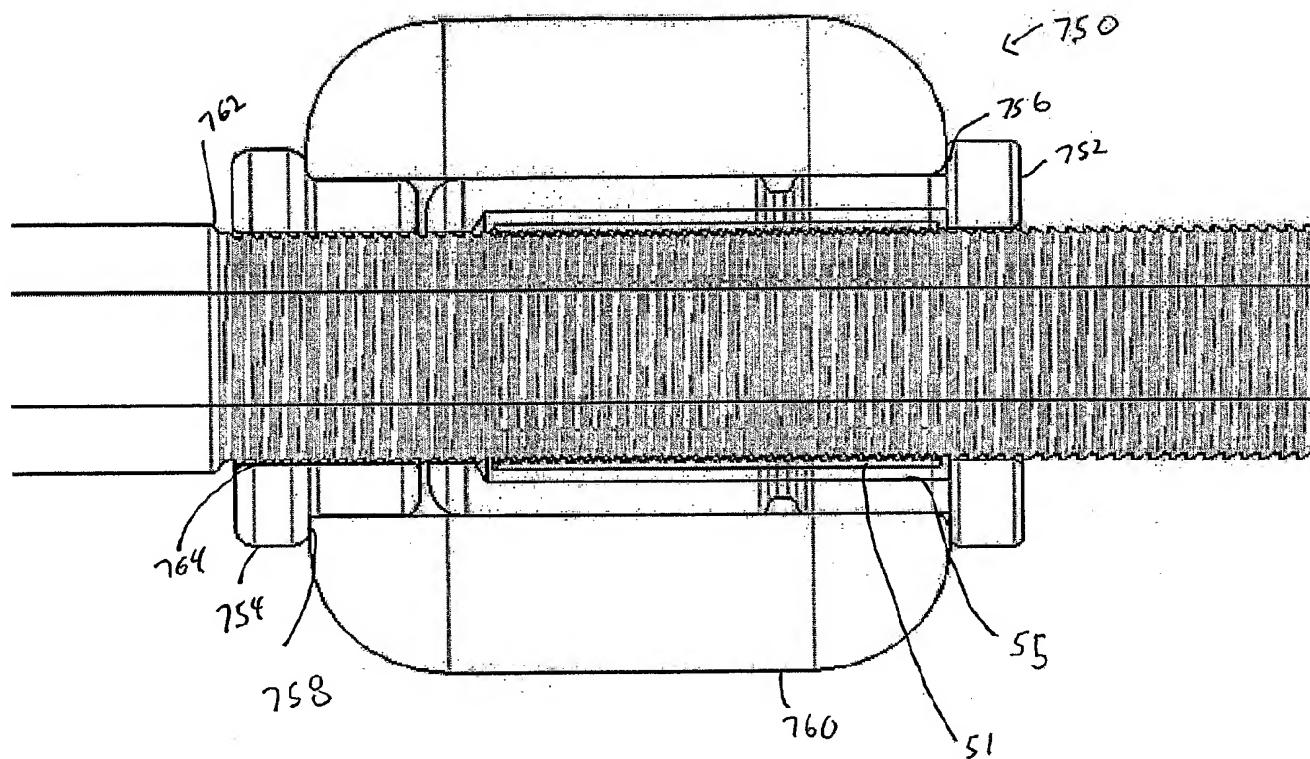


Fig. 20D

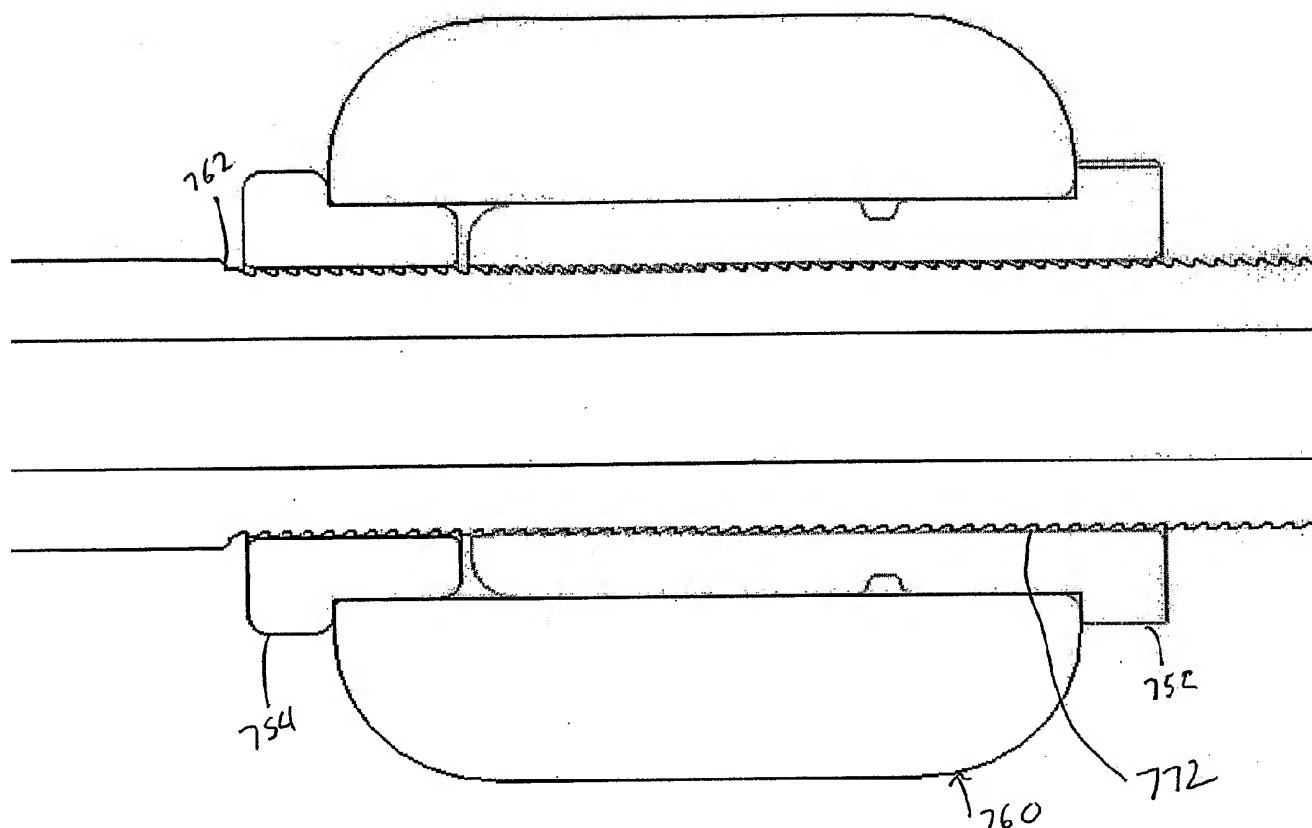


Fig. 21

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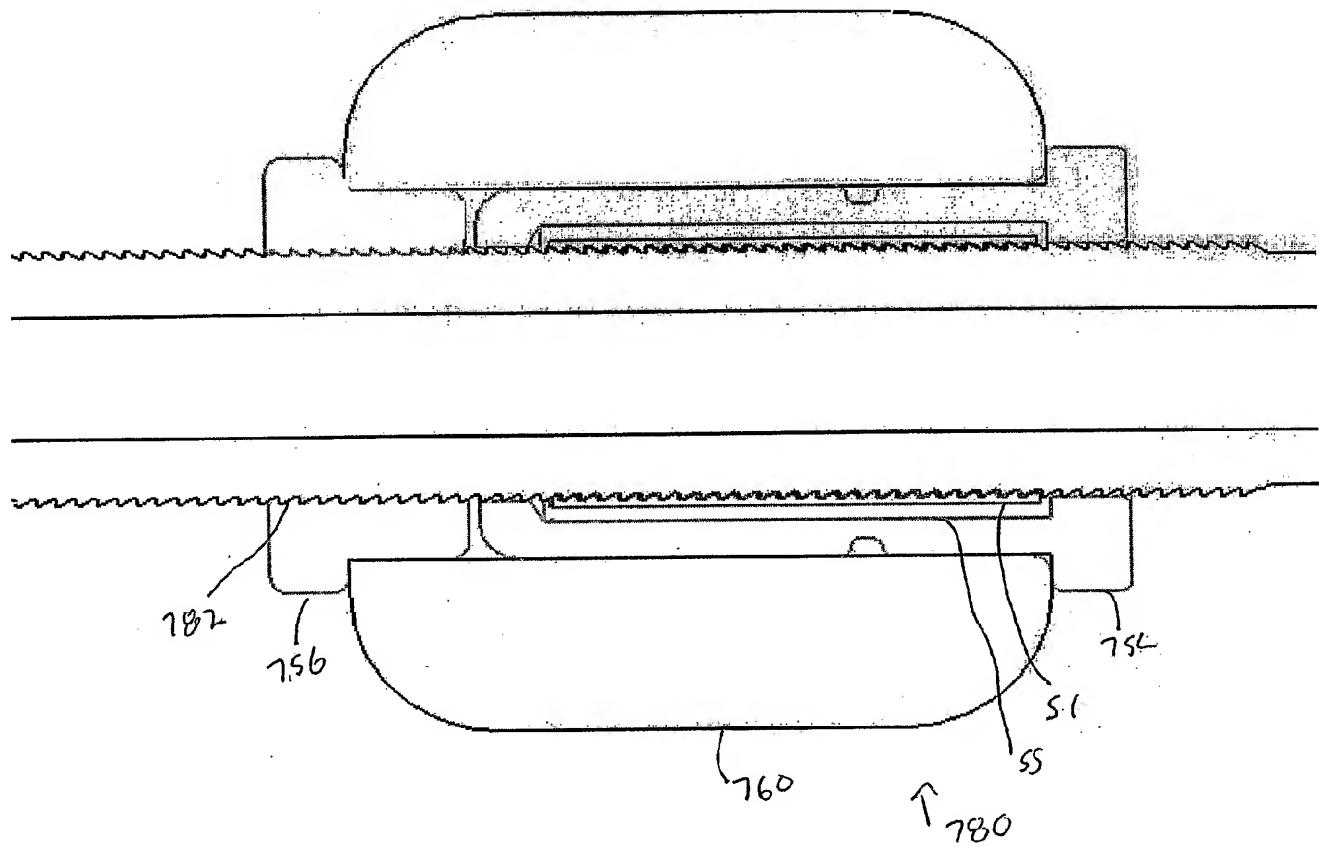


Fig. 22

# INTERNATIONAL SEARCH REPORT

national application No  
T/US2005/044321

## A. CLASSIFICATION OF SUBJECT MATTER

A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/008949 A (TRIAGE MEDICAL, INC; CULBERT, BRAD; STEVENS, BRUCE, EDWARD) 29 January 2004 (2004-01-29) figures 1-6F ----- US 5 667 508 A (ERRICO ET AL) 16 September 1997 (1997-09-16) figures 1a,2-4 -----	10-15, 19-22, 66-68
X		10,12, 13,15, 19-22



Further documents are listed in the continuation of Box C.



See patent family annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

4 April 2006

Date of mailing of the international search report

13/04/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Hamann, J

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2005/044321

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 1–9, 16–18, 23–39, 46–58  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

national application No

T/US2005/044321

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 2004008949	A	29-01-2004	AU	2003261286 A1		09-02-2004
			EP	1523278 A2		20-04-2005
			JP	2005533627 T		10-11-2005
US 5667508	A	16-09-1997	AT	283669 T		15-12-2004
			AU	2750097 A		19-11-1997
			DE	69731831 D1		05-01-2005
			DE	69731831 T2		15-12-2005
			EP	0904026 A1		31-03-1999
			ES	2230602 T3		01-05-2005
			HK	1018196 A1		15-07-2005
			JP	2000509303 T		25-07-2000
			WO	9740762 A1		06-11-1997